Cancer Biomedical Informatics Grid (caBIG™)

2006 Strategic Plan

April 6, 2006

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Introduction to the caBIG™ Strategic Plan

The Strategic Plan sets a clear strategic direction for caBIG™; it is a living document – one which will evolve as caBIG™ evolves. The caBIG™ 2006 Strategic Plan presents caBIG's™ mission, vision, strategic priorities, and goals.

Subsequent sections of this Strategic Plan:

- Communicate caBIG's™ mission;
- Describe caBIG's™ vision;
- Highlight caBIG's™ primary Strategic Priorities and Strategic Goals;
- Detail the Principles and Emphases of caBIG™;
- Illustrate the execution of caBIG's™ goals;
- Outline the short-term, mid-term, and long-term strategic goals of caBIG™; and
- Describe the purpose and strategic goals of each caBIG™ Workspace.

Detailed implementation plans will be developed within the caBIG™ Workspaces and are beyond the scope of this document.

1.0 MISSION

caBIG™ participants will develop readily disseminated standards, tools, and information systems for the management of clinical and research activities in oncology. These will include systems for the management of cancer clinical trials, for integrative research systems, a coherent consistent approach to biospecimen informatics management, and the underlying architecture, vocabularies, standards, and data elements that will facilitate sharing and access to these systems.

2.0 VISION

The cancer Biomedical Informatics Grid (caBIG™) is a network of cancer research communities sharing common interests in the development of data standards, sharable interoperable architectures, and tools for managing and applying the information learned from cancer research.

caBIG™ Vision

caBIG™ will become a self-sustaining network, which will foster improvements in collaborative projects and increase the speed and efficacy of treatment to benefit patients.

3.0 caBIG™ Vision Detailed

(This section is currently being developed).

4.0 caBIG™ Strategic Priorities

caBIG's™ strategic priorities stem from caBIG's™ mission and vision. caBIG's™ primary strategic priorities are to:

- Illustrate that a spectrum of Cancer Centers with varying needs and capabilities can be joined in a common network or grid of shared data, applications, and technologies
- Demonstrate that Cancer Centers, in collaboration with NCI, will develop new enabling tools and systems that could support multiple Cancer Centers
- Demonstrate that Cancer Centers will actively use the network or grid and realize greater value in their cancer research endeavors by using the network
- Create an extensible infrastructure that will continue to be expanded and extended to members of the community

- Develop (or modify) biomedical research tools to support cancer research efforts and to meet needs identified by the cancer research community, including standards-based and components-based clinical trial management systems, tissue banks and pathology tools, and integrative cancer research applications

- Share biomedical research data according to agreed upon common standards and in a manner that protects patient data privacy and security

- Foster common usage of vocabularies, common data elements, and the formation of a unifying architecture for the caBIG™ community

caBIG's™ mission, vision, and strategic priorities directly align with caBIG's™ key strategic goals. Further, caBIG™ aligns with the key strategic goals and priorities of the US Department of Health and Human Services (HHS), the National Institutes of Health (NIH), the National Cancer Institute (NCI), and the National Cancer Institute Center for Bioinformatics (NCICB).

HHS pursues broad scientific advances to measurably reduce the burden of all chronic diseases. Specifically, HHS aims at improving the clinical research network to advance better prevention, early diagnosis, and treatment of disease, including cancer. NIH's Roadmap for Medical Research, a series of far-reaching initiatives intended to accelerate the pace of life science discovery from the bench into practice for the benefit of the public, identifies the creation of a national software engineering system as a key goal. Through a computer-based grid, biologists, chemists, physicists, computer scientists, and physicians anywhere in the country will be able to share and analyze data using a common set of software tools. NCI was established to carry out a National Cancer Program that includes both national and international research, data collection, and information dissemination efforts with the ultimate goal of eliminating suffering and death due to cancer. NCICB spearheads critical public-private partnerships to develop and disseminate informatics for managing, analyzing, and sharing the wealth of information generated in the fight against cancer.

5.0 caBIG™ Principles and Emphases

caBIG's™ principles and emphases provide concrete guidance to caBIG™ participants and community members and support the fulfillment of caBIG's™ mission and vision.

caBIG™ development is based on principles of:

- open source software
- open access to data
- open development, and
- federated systems

caBIG™ projects emphasize:

- rapid development of working systems;

- productive interactions between workspaces;
- strategic development, guided by the Strategic Level Workspaces; and
- comprehensive interoperability in both their operation (syntactic) and in their use of standardized terms and data structures (semantic)

6.0 caBIG™ Strategic Goals

caBIG's™ strategic goals support the strategic priorities and provide critical performance milestones.

6.1 Short-term Goals (2006 – 2007)

a. Promulgate Gold, Silver, and Bronze development project standards to the national cancer research community
b. Establish a mechanism for engaging the private sector, cancer research organizations not currently contracted under caBIG™, and other federal agencies and divisions into the caBIG™ community
c. Publish white paper on caBIG's™ Mission and Goals in a top-tier journal
d. Develop sufficient research tools and standards to have a positive impact on the cancer research community, as measured by adoption of relevant caBIG™ principles and available products within project proposals
e. Facilitate the adoption and use of caBIG™ interoperable tools and data sets within the caBIG™ community

6.2 Mid-term Goals (2008 – 2009)

a. Ensure widespread adoption of developer standards so that funded developer projects are operating under the Gold standard of compatibility
b. Develop mechanisms for deploying, promoting, and maintaining caBIG™ compliant technologies and established datasets within the oncology research community

6.3 Long-term Goals (2010 – 2011)

a. Ensure widespread adoption, dissemination, and use of caBIG™ interoperable tools, standards, and data sets within the larger cancer community, to include the biopharmaceutical industry, non-NCI cancer centers, and the national cancer research enterprise.

7.0 Execution of caBIG™ Goals

caBIG's™ goals are implemented in the nine caBIG™ workspaces:

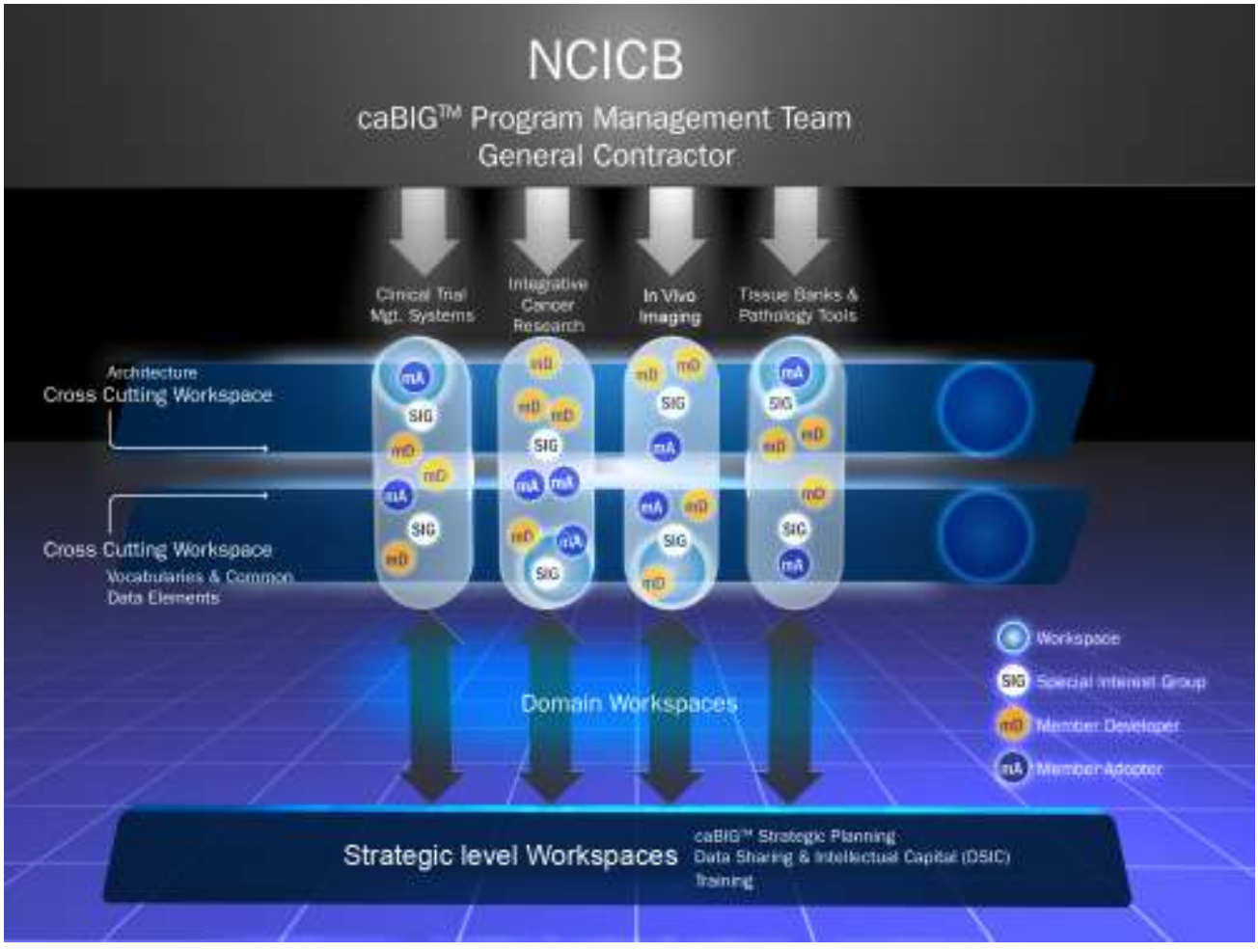
- Domain Workspaces
  - Integrative Cancer Research (ICR)
  - In Vivo Imaging (IMAG)
  - Clinical Trial Management Systems (CTMS)
  - Tissue Banks and Pathology Tools (TBPT)

- Crosscutting Workspaces
  - Architecture (ARCH)
  - Vocabularies and Common Data Elements (VCDE)

- Strategic Level Workspaces
  - Documentation and Training (D&T)
  - Data Sharing and Intellectual Capital (DSIC)
  - Strategic Planning (SP)

This organizational structure facilitates the development of communities of interest and expertise, the sharing of knowledge and information, and the strategic management of caBIG™.

Figure 1: caBIG™ Organization



8.0 Workspace Strategic Plans

The caBIG™ workspace strategic plans are presented in the following section. Each plan includes a description of the workspace and the activities currently being pursued, descriptions of SIGs in the workspace, and the workspace's goals. For each goal a performance metric/completion indicator, target completion date, and key dependencies and risks are noted. This information enables workspaces to track progress, identify issues, and develop issue resolution strategies within, and across, the workspaces.

9.0 Clinical Trial Management Systems Workspace

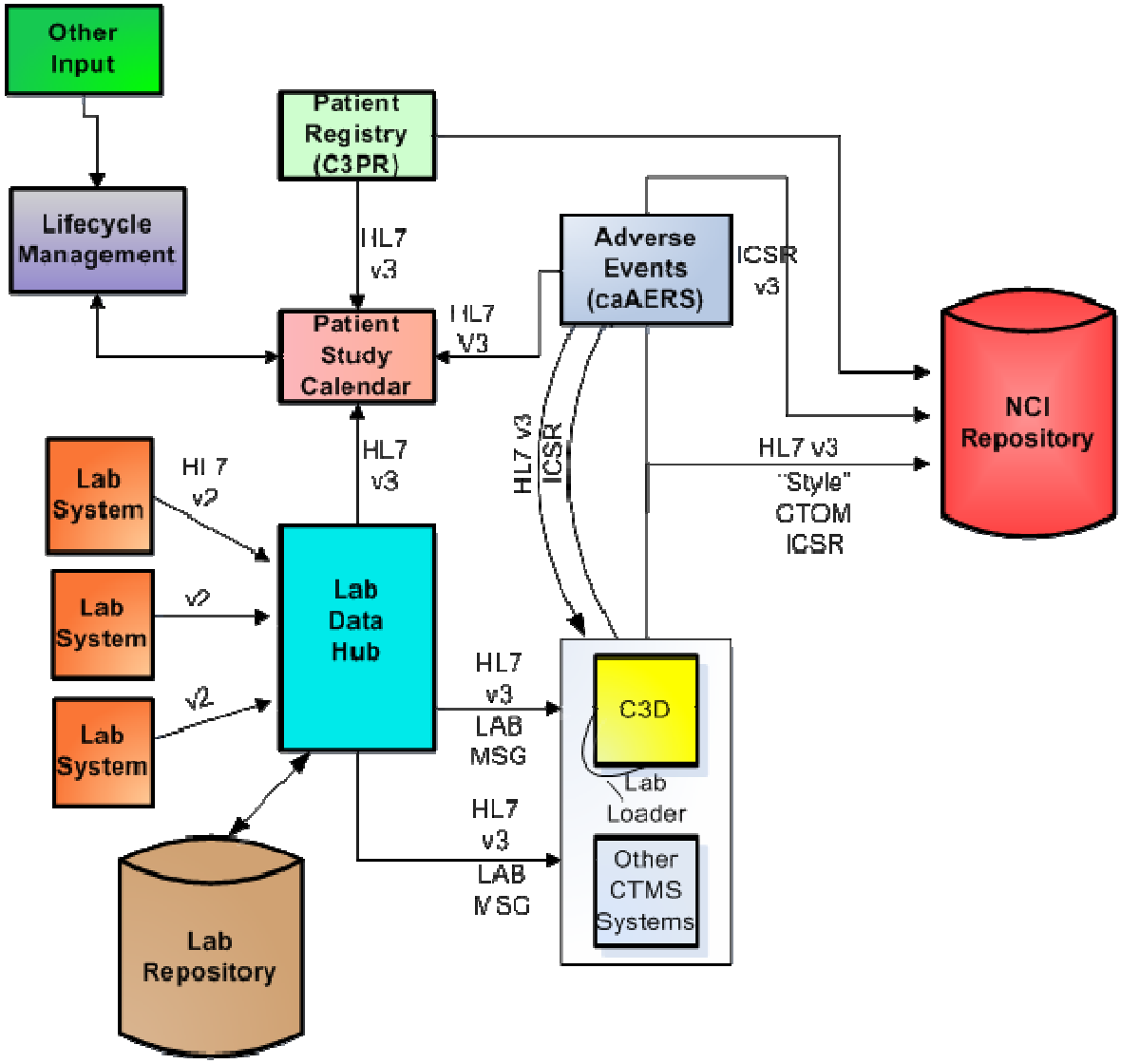
The Clinical Trial Management Systems (CTMS) Workspace (WS) is dedicated to increasing the pace of biomedical discovery by developing a comprehensive set of modular, interoperable, standards-based software applications to meet the diverse clinical trials management needs of the cancer research community. The CTMS WS promotes the ability to exchange clinical trials data securely and seamlessly, to efficiently implement and deploy clinical trials, and to analyze and disseminate research results over a Grid in a timely manner. The tools to be developed will enhance the capabilities of the ICR WS to conduct efficient translational research, be compatible with and utilize applications developed by the TBPT WS, and be supported by the work of the ARCH, VCDE, DSIC, TRNG, and SP Workspaces.

The primary goal of the CTMS WS is to develop and adopt interoperable, modular software applications that utilize a structured protocol framework. In so doing, the Workspace will take into account the diversity of clinical research activities and local practices, and make these applications configurable to meet the needs of Cancer Centers with little or no clinical data management tools in place, as well as those with robust clinical trials systems. Through the development of these applications, the CTMS WS will facilitate the establishment of a data repository will enable investigators to broaden the scope of their research and allow the pursuit of new research paradigms.

In addition, the CTMS WS will contribute to and adopt the tools and guidelines developed by the other Workspaces (e.g., ARCH, VCDE, DSIC, and TRNG), and develop synergies and maintain close interactions with the other Domain Workspaces (TBPT and ICR). The tools and standards developed will be harmonized with those of stakeholders concerned with the conduct of clinical trials, such as the National Cooperative Groups, Specialized Programs of Research Excellence (SPOREs), pharmaceutical companies, software vendors, the Food and Drug Administration (FDA), and the NCI community.

Figure 1 below outlines the critical path for the CTMS WS during caBIG's™ third year.

Figure 1. Year 3 CTMS Critical Path



CTMS SIG Descriptions

SIG Name	SIG Purpose/Description
Adverse Events	The Adverse Events (AEs) SIG is defining the requirements and providing input for a comprehensive, modular, automated solution for monitoring and managing AEs that emerge during clinical trials. The AEs SIG also generates reports for submission to internal and external regulatory monitoring organizations. Features will be developed based on the requirements defined by the community and with the ultimate goals of improving patient safety, increasing productivity, streamlining processing, and facilitating the sharing of adverse events information for research purposes.
Routine Data Exchange	The Routine Data Exchange SIG is defining the requirements for a regulatory reporting interface module to submit data electronically to NCI's Clinical Data Update System (CDUS), and the NCI's Clinical Trial Monitoring Service. This module will capture relevant data from multiple systems in multiple formats and translate them into the required formats. The process will be automated to improve workflow and reduce manual operations. Additionally, this module will allow the retention of data that is lost under current reporting mechanisms.
Laboratory Interfaces	The Laboratory Interfaces SIG is defining requirements for an automated, standards-based interface that will allow lab data across multiple systems and in multiple formats to be translated into common standards to facilitate automated lab data submission to clinical trials systems. The automated exchange of laboratory data is critical to improving workflow and promoting flexibility in the management of clinical trials data.
Financial/Billing	The Financial/Billing SIG is defining the requirements for a financial/billing module to meet identified needs and requirements of the Cancer Center community. Features will be developed as community needs are prioritized, but will likely include capabilities to monitor the alignment of clinical trials' plans, budgets, and actual expenditures, and to monitor financial billing compliance for clinical trials.
Structured Protocol Representation	The Structured Protocol Representation SIG is working to define needs for the components of a comprehensive clinical trials solution over the long-term. Developing a structured model for protocol representation is critical to this activity as protocol definition must be the foundation of any comprehensive clinical trials solution. A structured format enables improved interchange of data among systems and system components. Developers in the CTMS WS will work with various standards development efforts to identify elements of a clinical trial protocol that can be elucidated and codified to facilitate study design, regulatory compliance, project management, trial conduct, and data interchange among consumers and systems.

Study Calendar	The Study Calendar SIG is defining the requirements for a comprehensive clinical trials study calendar module that will interface with other expected components of a clinical trial management system. The module will address needs and requirements communicated by the cancer research community.

CTMS WS Goals

Program/Initiative: CTMS WS --Tool Development and Integration				
Goal 1 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Month/ Year)**	**Participants/ Contributors/Partners**	**Key Dependencies/Risks**
Lifecycle Management Identify the core set of elements from a protocol/study that are necessary for PIs to track progress and metrics on a study, or group of studies, and develop and deploy a module (dashboard) based on those requirements.	Delivery and acceptance of requirements by community. Delivery and acceptance of s/w. Acceptance by selected adopters. Interest by other members of community.	3/07	TBD – members of community to define requirements.	Interest among community to adopt the module. Interest among community to participate in requirements definition.
Goal 2 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Month/ Year)**	**Participants/ Contributors/Partners**	**Key Dependencies/Risks**
Patient Study Calendar Develop and deploy a module to support a specific set of prioritized requirements to support study calendar activities that will include Health Level Seven (HL7) v3 messaging.	Delivery and acceptance of requirements by community. Delivery and acceptance of s/w. Acceptance by selected adopters. Interest by other members of community.	3/07	Participants on the Study Calendar SIG. Award recipient of the RFP to do the development.	Complete and vetted requirements definition. Successful proposals in response to the RFP.
Goal 3 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Month/ Year)**	**Participants/ Contributors/Partners**	**Key Dependencies/Risks**
Adverse Events Reporting System Develop and deploy a prototype AE reporting module that will include HL7 v3 messaging.	Delivery and acceptance of requirements by community. Delivery and acceptance of s/w. Acceptance by selected adopters. Interest by other members of community.	3/07	Participants on the Adverse Event SIG. City of Hope.	Complete and vetted requirements definition. Successful proposals in response to the RFP.

Goal 4 Name & Description	Completion Indicator/ Performance Metric	Target Date (Month/ Year)	Participants/ Contributors/Partners	Key Dependencies/Risks
Lab Interface Develop and deploy a data hub module that will take in HL7 v2.x lab messages, convert them to HL7 v3 messages and interface with local clinical trial management systems.	Delivery and acceptance of requirements by community. Delivery and acceptance of s/w. Acceptance by selected adopters. Interest by other members of community.	3/07	Participants on the Lab Interface SIG. Award recipient of the RFP to do the development.	Complete and vetted requirements definition. Successful proposals in response to the RFP.

Program/Initiative: CTMS WS --Expanding and Improving CTMS Resources				
Goal 1 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Month/ Year)**	**Participants/ Contributors/Partners**	**Key Dependencies/Risks**
Use of GForge to Manage CTMS Requirements Use GForge to manage all CTMS requirements, and software to allow ready access to the CTMS participants. A convenient, consistent mechanism to access and improve caBIG™ tools will increase the consistency and build collaboration within WS and across caBIG™ activities.	All CTMS projects established in GForge	4/06	CTMS WS Participants	Get WS trained on the use of GForge
Goal 2 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Month/ Year)**	**Participants/ Contributors/Partners**	**Key Dependencies/Risks**
SIG Structure Evaluate the structure of the Workspace SIGs to best support the current workspace priorities. The Workspace structure should support workspace goals.	Document changes to SIG structure	4/06	CTMS WS Participants	Will depend on new projects initiated in the Workspace

Goal 3 Name & Description	Completion Indicator/ Performance Metric	Target Date (Month/ Year)	Participants/ Contributors/Partners	Key Dependencies/Risks
BRIDG Model Continue building and expanding the Biomedical Research Integrated Domain Group Model (BRIDG) model to support interoperability based on standards and provide a framework for the model driven development approach.	Delivery and acceptance of requirements by community. Delivery and acceptance of s/w. Acceptance by selected adopters. Interest by other members of community.	3/07	All. The SIGs should be basing their models on the BRIDG and collaborating with BRIDG to expand the model where necessary.	Meaningful collaboration among the community. Ability to find the necessary resources to support the harmonization efforts.
Goal 4 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Month/ Year)**	**Participants/ Contributors/Partners**	**Key Dependencies/Risks**
Increase WS participation Develop and execute a plan to increase WS Participation. Campaigns may include increased adoption of C3D and other modules as developed; increased participation in developing and vetting SOPs.	Measured increase in adoption of CTMS tools. Measured increase in BP/SOP SIG.	3/07	WS participants	Interest in community to adopt tools. Consensus among community on best practices and SOPs
Goal 5 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Month/ Year)**	**Participants/ Contributors/Partners**	**Key Dependencies/Risks**
Clinical Trial Reporting Continue to support the definition of requirements for a module to consolidate and simplify regulatory reporting including, but not limited to: CDUS and Summary 3 & 4.	Delivery and acceptance of requirements by community. Delivery and acceptance of s/w. Acceptance by selected adopters. Interest by other members of community.	3/07	Participants on the RDX SIG	Complete and vetted requirements definition

Goal 6 Name & Description	Completion Indicator/ Performance Metric	Target Date (Month/ Year)	Participants/ Contributors/Partners	Key Dependencies/Risks
Financial Billing Continue to support the definition of requirements for a module to support financial billing.	Delivery and acceptance of requirements by community. Delivery and acceptance of s/w. Acceptance by selected adopters. Interest by other members of community.	3/07	Participants on the Financial Billing SIG	Complete and vetted requirements definition

Program/Initiative: CTMS WS --Engagement of External Organizations				
Goal 1 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Month/ Year)**	**Participants/ Contributors/Partners**	**Key Dependencies/Risks**
Silver and Gold Compliance Certification Model Work with the crosscutting workspaces to establish a caBIG™ (Silver and Gold) compliance certification method. A consistent certification method will support engagement of external organizations.	Documented (Silver and Gold) compliance certification method	1/07	TBD	None identified
Goal 2 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Month/ Year)**	**Participants/ Contributors/Partners**	**Key Dependencies/Risks**
Standards for Common Data Elements Continue to work with VCDE WS to promote standards for common data elements to achieve semantic interoperability, in support of the overall goals of caBIG™. Continuing to agree on common semantics for data types will improve integration and collaboration	Additional sets of CDEs proposed as development of CTMS tools progress	3/07	WS Participants	Achieving consensus among community on terms

10.0 Integrative Cancer Research Workspace

The primary goal of the Integrative Cancer Research (ICR) Workspace is to provide a set of interoperable tools to store, link, and analyze diverse data resources to enable translational and integrative research. Achieving this goal will facilitate an integrated approach to cancer research, bringing diverse resources together seamlessly to promote the development of new biomarkers and new therapeutics to improve patient care. Three major capabilities will enable integrated cancer research; the capability to:

- Capture data from emerging high-throughput techniques.
- Link data from these techniques with federated data from the CTMS WS, the TBPT WS, and the IMAG WS.
- Analyze high-throughput and integrated data sets.

The ICR WS will create tools to support each of capabilities; the WS is developing well-documented and validated biomedical informatics toolsets and datasets for use throughout the research community. These toolsets are being developed using the enterprise-scale engineering best practices. To support semantic interoperability, the ICR WS collaborates with the VCDE WS to identify common data elements and controlled vocabularies to adopt as standards across the WS and ultimately across caBIG™. In addition, the ICR WS works closely with the ARCH WS to ensure that tools and systems are designed to function smoothly on the Grid.

During Years 1 and 2 of the caBIG™ pilot, the ICR WS focused on the creation of tools to support the capture and analysis of genomic and functional genomic data. This included tools and repositories for microarray data, proteomics data, biochemical and signaling pathways, and genomic annotations. The WS also adopted a number of standards for the exchange of information to support the syntactic and semantic interoperability of these resources. In Year 3 and beyond, the WS will build on the successes of Years 1 and 2 by pursuing the goals outlined in the following section.

ICR SIG Descriptions

SIG Name	SIG Purpose/Description
Pathways	The Pathway SIG supports basic research by helping to provide the cancer research community with easy access to pathway data and commonly used pathway analysis tools. Current projects directed by the SIG focus on tools for visualizing protein interactions and exchanging pathway information; tools for pathway modeling; and a database of biological pathways. These tools will be modified to work with other tools using caBIG™ exchange formats.
Microarray Repositories	The Microarray Repositories SIG identifies and prioritizes the needs of the larger cancer research community with respect to the capture, storage, and utilization of microarray data and related genetic data. The caArray repository, developed by the NCICB, is a key focus of the SIG and is being adopted by a number of groups, including tool developers. These developers are using caArray to analyze microarray data.
Genome Annotation	The Genome Annotation SIG provides data and tools to support cancer centers' efforts to incorporate genomics information into their research efforts. Standardized access to gene annotations and genomic data sources will support a consistent view of all available gene information. Tools directed by this SIG are focused on updating annotations on gene lists; gathering information for probes on a microarray from multiple databases into a single view; facilitating the maintenance of local and global annotations within a single system; providing information on proteins; and linking genomic identifiers across disparate data sources. This group will also identify and develop standards to promote semantic and syntactic interoperability among these resources.
Data Analysis and Statistical Tools	The Data Analysis SIG serves the needs of key end users - experimentalists and data analysts - by providing interoperable tools and associated standards, documentation, and training. The increased complexity and volume of data sets resulting from high-throughput measurement technologies is driving the need for increasingly sophisticated analytical tools. Tools are primarily focused on microarray data analysis, although some tools are designed for heterogeneous data sources. Systems in this group are being migrated from proprietary to open source. Open source systems can read-in data from caBIG™ compliant data sources, including caArray.

Proteomics	The Proteomics SIG provides data, tools, and standards to support cancer centers' efforts to incorporate proteomics information into their research efforts. Current projects focus on data and information management and data analysis. Projects vary from early development to fully-developed systems that will soon be ported to a caBIG™-compliant form.
Translational Tools	The Translational Tools SIG focuses on tools and technologies which are necessary for cancer centers to integrate clinical data with experimental data, and assuring that clinical data and studies more effectively utilize genomics and proteomics research data in cancer research and patient care. This SIG's activities are on hold pending the initiation of a translational project in caBIG™ and will reconvene when such a project is started (anticipated April, 2006).

ICR WS Goals

Program/Initiative: ICR WS --Data and Tool Integration				
Goal 1 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Month/Year)**	**Participants/ Contributors/Partners**	**Key Dependencies/Risks**
Provision of Relevant Cases Provide the caGrid Workflow team with scientifically relevant use cases -- the Grid will provide the most value to the cancer research community if it is designed to support the real needs of cancer researchers.	8 use cases delivered to the caGrid Workflow team, used to inform the Workflow architecture	2/06	ICR WS Participants	None identified
Goal 2 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Month/Year)**	**Participants/ Contributors/Partners**	**Key Dependencies/Risks**
caGRID Workflow Test the implemented caGrid workflow to ensure that it supports scientifically relevant use cases -- the Grid will provide the most value to the cancer research community if it supports the real needs of cancer researchers.	ICR Workflows are shown in a caGrid workflow presentation	10/06	ICR WS Participants	Sufficient Grid resources available to support scientifically relevant workflows in this timeframe
Goal 3 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Month/Year)**	**Participants/ Contributors/Partners**	**Key Dependencies/Risks**
Translational Informatics Project Initiate a Translational Informatics project in ICR, in support of the key goals of caBIG™. Data integration is a barrier faced by translational researchers and lowering this barrier is a key goal of caBIG™.	Task order issued for Translational Informatics project	4/06	TBD	Receipt of one or more appropriate RFP responses

Goal 4 Name & Description	Completion Indicator/ Performance Metric	Target Date (Month/Year)	Participants/ Contributors/Partners	Key Dependencies/Risks
Workflow Navigation Map Develop a workflow navigation map (diagram) for ICR data and tools to facilitate researchers' integrative use of ICR tools and data	Deploy navigation map onto web site with embedded links to tools and data	8/06	ICR WS Participants	Building consensus among ICR participants regarding the appropriate workflow model

Goal 5 Name & Description	Completion Indicator/ Performance Metric	Target Date (Month/Year)	Participants/ Contributors/Partners	Key Dependencies/Risks
Interoperability of Proteomics Tools and CPAS Determine which (if any) proteomics tools should be interoperable with CPAS (Computational Proteomics Analysis System from FHCRC). The ability to analyze, store and manage proteomics data in a scientific workflow driven process promotes interoperability.	Assessment of value document Extension (or new) Statements of Work (SOWs) for caBIG™ proteomics projects	10/06	TBD	- Funding will depend on available budgets and value of interoperability to broader community. - Availability and cooperation of CPAS staff
Goal 6 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Month/Year)**	**Participants/ Contributors/Partners**	**Key Dependencies/Risks**
ICR Resources User Interface Create an application that provides a friendly user interface to navigate ICR resources integrated through the use of common data elements. Interoperable tools will be of most benefit if they can be accessed and used by bench scientists and clinicians.	Application that integrates at least 5 ICR resources demoed at a F2F meeting	6/07	TBD	None identified
Goal 7 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Month/Year)**	**Participants/ Contributors/Partners**	**Key Dependencies/Risks**
Federating TBPT and ICR Data Use caGrid resources to perform an analysis by federating TBPT data and ICR data through the use of common data elements. The integration of basic research data with tissue pathology data supports the overall translational research goals of caBIG™.	Manuscript describing the analysis results	6/07	TBD	- Will need to specifically fund such an effort - Requires a driving use case

Goal 8 Name & Description	Completion Indicator/ Performance Metric	Target Date (Month/Year)	Participants/ Contributors/Partners	Key Dependencies/Risks
Federating ICR, TBPT, and CTMS Data Use caGrid resources to perform an analysis by federating ICR, TBPT and CTMS data through the use of common data elements. The integration of basic research data with tissue pathology data and clinical data supports the overall translational research goals of caBIG™.	Manuscript describing the analysis results	1/08	TBD	- Will need to specifically fund such an effort - Requires a driving use case - Need harmonized object models to automatically link data across applications
Goal 9 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Month/Year)**	**Participants/ Contributors/Partners**	**Key Dependencies/Risks**
Methodology for Gaining Feedback on Usage of caBIG™ Resources Develop a methodology for gaining feedback on the usage of caBIG™ resources. An accurate method for assessing the usage of caBIG™ resources will help to measure effectiveness.	Documented methodology	12/07	TBD	None identified
Goal 10 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Month/Year)**	**Participants/ Contributors/Partners**	**Key Dependencies/Risks**
Use of Interoperable Grid-Based Resources at Cancer Centers Encourage regular use of interoperable grid-based resources at Cancer Centers, to support their research objectives. The use of caBIG™ tools in the everyday research at cancer centers is a key objective of caBIG™.	Five cancer centers are regularly accessing the Grid. The methodology in Goal 9 above will be used to measure this.	1/09	TBD	Dependent on Goal 9, above

Goal 11 Name & Description	Completion Indicator/ Performance Metric	Target Date (Month/Year)	Participants/ Contributors/Partners	Key Dependencies/Risks
Use of caBIG™ Resources to Improve Patient Care Demonstrate that caBIG™ resources are being used to improve patient care – the ultimate goal of caBIG™.	Manuscript(s) documenting these results	1/10	TBD	None identified

Program/Initiative: ICR WS --Adding to/Improving ICR Resources				
Goal 1 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Month/Year)**	**Participants/ Contributors/Partners**	**Key Dependencies/Risks**
Gap Analysis of ICR Resources Perform a gap analysis of current ICR resources and identify additional types of resources needed to enrich the Grid. The Grid will be of greater utility to cancer researchers when complete workflows can be supported	Document describing the analysis	3/06	ICR WS Participants	May be difficult to reach consensus on this gap analysis
Goal 2 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Month/Year)**	**Participants/ Contributors/Partners**	**Key Dependencies/Risks**
Proteomics Repository Devise a strategy for bringing a proteomics repository into caBIG™ compliance. Creating connectivity between caBIG™ tools and a proteomics repository promotes interoperability.	SOW issued for bringing a proteomics repository into caBIG™.	4/06	TBD	None identified

Goal 3 Name & Description	Completion Indicator/ Performance Metric	Target Date (Month/Year)	Participants/Contributors/ Partners	Key Dependencies/Risks
Use of GForge to Manage ICR Software Use GForge to manage all ICR software, to allow ready access to the ICR toolset. A convenient, consistent mechanism to access and improve caBIG™ tools will increase the benefit they provide to all researchers.	All ICR projects established in GForge	4/06	ICR WS Participants	Get WS trained on the use of GForge
Goal 4 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Month/Year)**	**Participants/ Contributors/Partners**	**Key Dependencies/Risks**
SIG Structure Redefine the structure of the WS SIGs to best support the current WS priorities. The WS structure should support WS goals.	New structure documented	4/06	ICR WS Participants	Will depend on new projects initiated in the Workspace

Goal 5 Name & Description	Completion Indicator/ Performance Metric	Target Date (Month/Year)	Participants/ Contributors/Partners	Key Dependencies/Risks
Workspace Structure Implementation Implement the revised Workspace structure	New structure implemented	6/06	ICR WS Participants	Depends on the preceding goal
Goal 6 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Month/Year)**	**Participants/Contributors/ Partners**	**Key Dependencies/Risks**
Interoperability of ICR Microarray Resources Roadmap Develop a roadmap for interoperability of ICR microarray resources. Microarray data is a key research tool of cancer biologists and ready storage, access and analysis of this data is an important need	Roadmap document posted on caBIG™ website	6/06	ICR WS Participants	None identified
Goal 7 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Month/Year)**	**Participants/Contributors/ Partners**	**Key Dependencies/Risks**
Standards for Common Data Elements Continue to propose standards for common data elements to promote semantic interoperability, in support of the overall goals of caBIG™. Continuing to agree on common semantics for data types will improve integration and collaboration.	Five additional sets of CDEs proposed as standards in 2006	12/06	ICR WS Participants	Difficult to get WS consensus on standards

Goal 8 Name & Description	Completion Indicator/ Performance Metric	Target Date (Month/Year)	Participants/Contributors/ Partners	Key Dependencies/Risks
Year 1 ICR Projects Grid enable Year 1 ICR Projects – this directly supports the program goal of establishing a cancer bioinformatics grid.	75% of Year 1 projects grid-enabled (targeting caGrid 0.5)	12/06	Year 1 project developers	Defining projects of highest priority for grid enablement
Goal 9 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Month/Year)**	**Participants/Contributors/ Partners**	**Key Dependencies/Risks**
Use Cases Provide use cases, to the caGrid team, that support the need for grid computing resources. Computing resources are needed to support many computationally intensive ICR tools.	5 uses cases supplied to the caGrid team	12/06	ICR WS Participants	None identified
Goal 10 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Month/Year)**	**Participants/Contributors/ Partners**	**Key Dependencies/Risks**
Crosscutting Best Practices SIG Provide the crosscutting Best Practices SIG with requirements for standard GUI conventions for caBIG™ resources, to promote usability.	Requirements document provided to the crosscutting Best Practices SIG	12/06	ICR WS Participants	- Agreeing upon GUI conventions may be a challenge

Program/Initiative: ICR WS --Engagement of External Organizations				
Goal 1 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Month/Year)**	**Participants/ Contributors/Partners**	**Key Dependencies/Risks**
Silver and Gold Compliance Certification Method Work with the crosscutting workspaces to establish a caBIG™ (Silver and Gold) compliance certification method. A consistent certification method will support engagement of external organizations.	Documented (Silver and Gold) compliance certification method	1/07	TBD	None identified

Goal 2 Name & Description	Completion Indicator/ Performance Metric	Target Date (Month/Year)	Participants/ Contributors/Partners	Key Dependencies/Risks
Query Cancer Community for Necessary Tools Query the cancer research community to identify tools they would like to have on the Grid. The Grid will be of greater utility to cancer researchers when the key tools used by these groups are available in this environment	Query responses available on the caBIG™ website	10/06	TBD	Can be difficult to get researcher to respond to such surveys
Goal 3 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Month/Year)**	**Participants/ Contributors/Partners**	**Key Dependencies/Risks**
Incorporating Tools into caBIG™ Create a plan for the incorporation of the tools, noted in Goal 2, into caBIG™.	Documented plan presented at a caBIG™ meeting	4/07	TBD	Dependent on the preceding goal

Goal 4 Name & Description	Completion Indicator/ Performance Metric	Target Date (Month/Year)	Participants/ Contributors/Partners	Key Dependencies/Risks
Making Non-caBIG™ Funded Tools/Dataset Compliant Implement the plan described in Goal 3, to engage non-caBIG™-funded, non-commercial groups in making their tools/datasets caBIG™-compliant. Bringing more tools/datasets into caBIG™ will further the programs goals of interoperability and thus support the integration efforts of cancer researchers.	Development project(s) from outside groups documented on the caBIG™ website	12/07	TBD	- Mechanism must be determined - Method for assessing/certifying caBIG™ compliance
Goal 5 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Month/Year)**	**Participants/ Contributors/Partners**	**Key Dependencies/Risks**
Engaging Industry Partners Implement the plan described above to engage industry partners in making their tools/datasets caBIG™-compliant. There are outstanding tools developed by the commercial sector and it will greatly benefit cancer researchers if these are interoperable with other caBIG™ tools.	Development project(s) from industry partners documented on the caBIG™ website	12/07	TBD	- Address Intellectual Property (IP) and licensing issues - Architecture is foreign to most company's software development policies. - Method for assessing/certifying caBIG™ compliance
Goal 6 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Month/Year)**	**Participants/ Contributors/Partners**	**Key Dependencies/Risks**
Plan for Educating Community on caBIG™ Resources Provide the SP WS with requirements for a plan to educate the cancer research community on the availability of caBIG™ resources	Documented requirements sent to the SP WS.	1/07	ICR WS Participants	None identified

10.1 Population Sciences SIG

The goal of the Population Sciences (PS) SIG is to provide a set of interoperable tools for study administration and data sharing that support the various health disciplines represented by the SIG. The PS SIG's goals are presented separately because their content differs significantly from the other goals of the ICR WS. Population Sciences are an integral component of cancer research and represent key elements in the bridge between clinical/basic research and cancer control. The PS SIG aims to advance the various disciplines of population sciences by developing tools and creating data standards that operate within caBIG™ and leverage existing caBIG™ activities and resources to address the common needs of these disciplines. The PS SIG will use models to develop or adopt tools for creating, deploying, and administering applications for: data collection and retrieval; study administration and execution; data sharing and transmission; and communication with cancer registries and other data resources. The following strategic goals highlight how the PS SIG will implement its activities.

PS SIG Goals

Program/Initiative: PS SIG --PS Tools, Models and Standards Development				
Goal 1 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Month/Year)**	**Participants/ Contributors/Partners**	**Key Dependencies/Risks**
Issue Population Sciences RFP Issue RFP for the development of tools, models and data standards to support the needs of the SIG.	Population Sciences RFP issued	4/06	- NCI - Booz Allen Hamilton (BAH)	- Ability to come to consensus on language and scope of RFP.
Goal 2 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Month/Year)**	**Participants/ Contributors/Partners**	**Key Dependencies/Risks**
Enable Integration with caDSR Evaluate potential for integration of existing tools with the cancer Data Standards Repository (caDSR) based on work by two communities. Provide recommendations for solutions to issues raised and develop standards/models for caDSR and caBIG™ questionnaire building tools to support population sciences communities' research	SOW issued to complete this task	2/06	- SIG Members - NCI - BAH	- Short-time frame for task completion
Goal 3 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Month/Year)**	**Participants/ Contributors/Partners**	**Key Dependencies/Risks**
Population Sciences Data Modeling Capability Create a community to support the development of a model for execution and management of population studies and assess the utility of models from the CTMS WS in population studies.	Formation of Data Standards sub-group. Creation of models for community needed elements	10/06	- SIG Members - NCI	- Community consensus around parameters for data modeling

Goal 4 Name & Description	Completion Indicator/ Performance Metric	Target Date (Month/Year)	Participants/ Contributors/Partners	Key Dependencies/Risks
Questionnaire Generation Tool Develop the requirements needed to create a tool to generate questionnaires using caDSR and other interoperable data element repositories.	Formation of Study Instruments Generation sub-group and Generation of tool	10/06	- SIG Members - NCI	- Community Acceptance of a standards and implementation plans
Goal 5 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Month/Year)**	**Participants/ Contributors/Partners**	**Key Dependencies/Risks**
Data Standards Create data standards to support Goals 3 and 4	Entry of the standards into the caDSR.	10/06	- SIG Members - NCI	- Community Acceptance of a standards and implementation plans
Goal 6 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Month/Year)**	**Participants/ Contributors/Partners**	**Key Dependencies/Risks**
Population Sciences Data Sharing Enable solutions for data sharing through the creation of Population Sciences data repositories and methods for exposing registry data to caBIG™.	Formation of Data Sharing sub-group. Definition of methods for transmission and security	10/06	- SIG Members - NCI	- Community acceptance of data sharing standards, security, timing and protocol. - Education around methods to access national cancer registry data (SEER/NCI, NPCR/CDC, NAACCR data files).

Program/Initiative: PS SIG --Integrate Population Sciences into caBIG™ Community				
Goal 1 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Month/Year)**	**Participants/ Contributors/Partners**	**Key Dependencies/Risks**
Population Sciences and caBIG™ Integration Determine interoperability points with other caBIG™ tools and systems	Develop White Paper to report to the community touch points within caBIG™	DRAFT 1.0 by 4/06	- SIG Members	- An ideal pairing might not exist - Ability to identify and promote multiple synergies

Goal 2 Name & Description	Completion Indicator/ Performance Metric	Target Date (Month/Year)	Participants/ Contributors/Partners	Key Dependencies/Risks
Harmonization of Efforts with the caDSR Development Team Sync Population Sciences SIG activities with the development of the caDSR.	Formation of PS / caDSR sub-group	6/06	- SIG Members - NCI	- Divergence in the plans and needs of both groups. - Ability to accommodate possible needs of PS communities within overall caDSR structure.
Goal 3 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Month/Year)**	**Participants/ Contributors/Partners**	**Key Dependencies/Risks**
Open Population Sciences and External Workspace Communications Strengthen Relationships between CTMS and the PS SIG, particularly through awareness of the BRIDG model.	Creation of PS / CTMS sub-group	6/06	- SIG Members - NCI	- Ability to identify synergies between workspaces
Goal 4 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Month/Year)**	**Participants/ Contributors/Partners**	**Key Dependencies/Risks**
Biospecimen Integration Efforts Strengthen Relationships between TBPT and the PS SIG, particularly through awareness of caTISSUE, caTIES and related tools. Determine which biospecimen data fields will be needed in PS applications.	Creation of PS/TBPT sub-group	6/06	- SIG Members - NCI	- Ability to identify synergies between workspaces

11.0 Tissue Banks & Pathology Tools Workspace

The primary goal of the Tissue Banks and Pathology Tools (TBPT) WS is the standardized development of biospecimen and pathology tools to enable specimen and information sharing across Cancer Centers. This effort includes:

- Building tools for the collection and annotation of biospecimens from Pathology (Clinical and Anatomic), Cancer Registry and other clinical systems with treatment, progression and outcomes data
- Developing the means to share specimens between centers, support queries to identify specimens available for a particular study, and provide "honest broker" tools to facilitate specimen requests and distribution of requests to source sites
- Integrating existing biospecimen software (e.g. inventory, pathology report data, and clinical annotations on treatment, progression and other outcomes measures)
- Creating a plan for the integration of biospecimen data with other genomic, proteomic and metabolomic data collected during translational science discovery and validation research
- Establishing a culture of data sharing through biospecimen infrastructure (this is a critical role of the new Office of Biorepositories and Biospecimen Research).

Biospecimens have long been critical to cancer research, and are even more so now, during the "–omics" era of cancer research. The TBPT WS works to standardize biospecimen associated information and pathology informatics tools in order to share the individual collections of biospecimens and associated annotations. This effort will further enhance collaborative tissue based research for cancer prevention and treatment. The adoption of standardized tools to manage the storage, distribution and clinical annotation of tissue and associated information is one of the central tenets of the caBIG™ strategy. These tools will outfit a spectrum of cancer researchers including those who need manual data entry for their current environment and semi-automated methods for centers who have already developed tools and want to share them with the greater cancer community. Ultimately, the WS anticipates that all cancer researchers will utilize automated systems interfaced to translational research and clinical cancer informatics environments, resulting in a single point of entrance to federated tissue banks and pathology systems across the country. A single point of entry will allow researchers to more effectively locate and analyze biospecimens for use in cancer research based on anatomic pathology, laboratory medicine, patient data, and experimental results.

The TBPT WS is focused on the development of a scalable set of caBIG™-compliant tissue banking tools. The systems will be based on three primary components:

1. caTIES (Developer: University of Pittsburgh) – The cancer Text Information Extraction System provides a computational means to structure and code data contained within free text Surgical Pathology Reports (SPR). These coded SPRs can then serve as a primary means to provide anatomic pathology annotations to tissue specimens.

2. caTISSUE Core (Developer: Washington University) – This system will be the core solution for biospecimen inventory, tracking, and basic annotation for use by biospecimen resource facilities. As with all other caBIG™ developed applications, caTISSUE will be n-tier, and grid-enabled, allowing for access to and management of samples from any geographic location.

3. caTISSUE Clinical Annotation Engine (CAE) (Developer: University of Pittsburgh) – This system will serve as the main annotation engine for caTISSUE, and will primarily deliver clinically based annotations. Initially, caTISSUE CAE will focus on the association of biospecimens with data collected from the clinical Anatomic Pathology and Clinical Pathology Laboratory Information Systems and the hospital cancer registry, as well as other outcome data stored in Radiology, Radiation Oncology, Electronic Medical Record and other source systems. caTISSUE CAE can function in a standalone mode, providing annotations to other proprietary biospecimen management systems. Ideally, it will be integrated with caTISSUE Core and caTIES to deliver a comprehensive solution.

These projects are supported by data derived from paraffin-embedded tissue archives provided by the University of Pennsylvania and the University of Pittsburgh.

TBPT WS Goals

Program/Initiative: TBPT WS --Primary Development Projects (PDP)				
Goal 1 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Month/ Year)**	**Participants/Contributors/ Partners**	**Key Dependencies/ Risks**
CaTISSUE Core Stable release of caTISSUE Core 1.0 caTISSUE Core is the primary biospecimen management tool, built from the ground up, based on caBIG™ compatibility guidelines. caTISSUE Core will provide an events-based platform for biospecimen management of all manner of specimens and specimen derivatives.	Stable release of first generation software that fully supports the use cases and specifications outlined by the workspace in the development documentation. Stable release includes testing of multiple developer releases of the software.	3/2006	Developers - Washington University Adopters – University of Pennsylvania, Thomas Jefferson University, Dartmouth University, University of North Carolina, Duke, Wake Forest, Indiana University,	Development under tight timelines Development occurring asynchronously with other development efforts
Goal 2 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Month/ Year)**	**Participants/Contributors/ Partners**	**Key Dependencies/ Risks**
Release of caTISSUE Clinical Annotation Engine (CAE) 1.0 caTISSUE CAE is a modular annotation engine that will integrate with caTISSUE Core, as well as stand-alone, for integration with third-party biospecimen management tools. The current version of CAE can handle annotations for breast, prostate, and melanoma specimens. The pathology model is based on the College of American Pathologists Protocols for their associated lesions.	Stable release of first generation software that fully supports the use cases and specifications outlined by the workspace in the development documentation. Stable release includes testing of multiple developer releases of the software.	3/2006	Developers - University of Pittsburgh Adopters – Northwestern University, Dartmouth University, Washington University	Development under tight timelines Development occurring asynchronously with other development efforts

Goal 3 Name & Description	Completion Indicator/ Performance Metric	Target Date (Month/ Year)	Participants/Contributors/ Partners	Key Dependencies/ Risks
Release of Cancer Text Information Extraction System (caTIES) 2.0 caTIES provides a robust platform to migrate free text based surgical pathology reports to concept coded, organized data structures. caTIES is a significant extension to SPINTies application developed through the Shared Pathology Informatics Network.	Stable release of second generation software that fully supports the use cases and specifications outlined by the workspace in the development documentation and is grid-enabled. Stable release includes testing of multiple developer releases of the software.	3/2006	Developers - Washington University, University of Pittsburgh Adopters – University of Pennsylvania, Thomas Jefferson University, Washington University	Development under tight timelines Development occurring asynchronously with other development efforts Dependent on availability of a de-identification tool
Goal 4 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Month/ Year)**	**Participants/Contributors/ Partners**	**Key Dependencies/ Risks**
Adoption of caTISSUE Components Support adoption of caTISSUE components including caTISSUE Core, CaTISSUE Clinical Annotation Engine, and caTIES at multiple sites. Identify 3-4 Cancer Centers for adoption of all 3 applications	Adopters completed software testing Software in use a adopter organizations Existence of appropriate support materials – documentation, training, etc.	3/2006 9/2006	Adopters – University of Pennsylvania, Thomas Jefferson University, Wake Forest University Dartmouth College, Indiana University, University of North Carolina, Duke University, and National Biospecimen Network (NBN) Prostate SPORE institutions	Establishment of Institutional Review Board (IRB)/Trust agreements between participating institutions – reference the collaboration Availability of a robust, open source de-identification tool

Goal 5 Name & Description	Completion Indicator/ Performance Metric	Target Date (Month/ Year)	Participants/Contributors/ Partners	Key Dependencies/ Risks
Extensibility and Usability Improve usability and extend capabilities of the initial versions of the applications i.e. new specimen types (caTissue Core), additional diseases (caTissue CAE). In keeping with the original vision, each caTISSUE component application needs to function in a stand-alone capacity to interoperate with legacy systems, as well as integrate seamlessly with each other	Revised versions of systems providing appropriate extensibility	12/2006	Washington University, University of Pittsburg Medical Center	Appropriate mechanisms for timely addition of CDEs. Streamlined/automated metadata curation.
Goal 6 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Month/ Year)**	**Participants/Contributors/ Partners**	**Key Dependencies/ Risks**
Grid Enablement of Tools Grid-enablement of caTISSUE Core and CAE	Ability to query and share data across institutions	12/2006	Washington University, University of Pittsburgh	Depends on release of caGRID 1.0 by Architecture Workspace
Goal 7 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Month/ Year)**	**Participants/Contributors/ Partners**	**Key Dependencies/ Risks**
Testing Applications Across Different Environments The 3 applications will be rolled out to different kinds of organizations to understand how the different environments in various Cancer Centers will affect use and future development.	Successful implementation in small as well as large Cancer Centers	12/2007	TBD	Lack of infrastructure at smaller sites may delay or prevent adoption

Program/Initiative: TBPT WS --Development of Integrated Tissue Banking Suite (ITB)				
Goal 1 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Month/Year)**	**Participants/Contributors/ Partners**	**Key Dependencies/ Risks**
Super-adopters Adoption of all 3 applications by at least 4 adopter sites for the purpose of integration specification and testing. This goal creates a broader platform for evaluating the needs behind the integration of the primary TBPT applications, as well as a mechanism for validating the delivered solution The goal is to have the 3 applications running/deployed at the adopter sites prior to integration of the applications from a programmatic perspective. This is to enable end-users to start using them and understand how they function together across sites, and to understand the use cases for their integration. Two separate goals were identified: 1. Evaluation of the applications internally from adopters perspective (what it takes to get the tool up and running) and collect important adoption parameters for the purpose of educating further development, future adoption as well as lessons learned for integration. 2. How to get the 3 tools working together while understanding their slightly different purposes.	Ability of researchers to identify specimens and cohorts across institutions. Pilot Comprehensive Cancer Centers to provide data and specimens through the grid to Cancer Centers with fewer resources.	6/2006	TBD	Release of stable versions of caTISSUE Core, CAE and caTIES. An integrated object model Resolution of a common hardware and software platform to carry out integration Appropriate environment in which to test the integrated components

Goal 2 Name & Description	Completion Indicator/ Performance Metric	Target Date (Month/ Year)	Participants/Contributors/ Partners	Key Dependencies/ Risks
Integrated Suite Development of Tissue Banking Suite (single unified system consisting of the three components – caTISSUE Core, caTIES, and caTISSUE Clinical Annotation Engine) The presentation layer of the integrate suite will maintain a single interface for all applications. The grid query interface should be leveraged to create the common interface for the purpose of minimizing redundant software development.	A common method for accessing related data across the various applications Development of a common interface based on the caGRID query interface Integrated caTISSUE Object Model Workflow Integration Delivery of caBIG™ compliant software	08/06 12/06 06/06 12/07	TBD	Integrated object models Harmonization of vocabularies and Common Data Elements Well developed and deployable grid query interface and query language specification

Program/Initiative: TBPT WS --Cross-Workspace Collaboration (CWC)				
Goal 1 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Month/Year)**	**Participants/Contributors/ Partners**	**Key Dependencies/Risks**
CTMS Connectivity Exchange of data with CTMS applications. Development and implementation of interfaces to the caBIG™ Clinical Trials tools and biospecimens collected as part of protocol based translational research.	Integrate TBPT OM with CTOM. Link CTMS laboratory interface to caTISSUE Clinical Annotation Module (Push and Pull) Make complete TBPT OM transparent to the CTMS application suite	06/08? 06/09? TBD	TBPT and CTMS Workspace developers and adopters	Harmonization of TBPT and Clinical Trials Object Models (CTOM) Potential lack of agreement on methodology and time-lines for integration Mature Application Programming Interfaces (APIs) from both TBPT and CTMS applications
Goal 2 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Month/ Year)**	**Participants/Contributors Partners**	**Key Dependencies/ Risks**
ICR Connectivity Exchange of genomic data with ICR applications such as caARRAY. This may be handled by the caTISSUE EAM development	Development and implementation of caTISSUE Core Experimental Annotations module which will facilitate data sharing with the tools of the ICR WS	03/07	TBPT and ICR WS developers and adopters	Harmonization of TBPT and ICR models or establishment of appropriate common objects for exchanging data Potential lack of agreement on methodology and time-lines for integration

Goal 3 Name & Description	Completion Indicator/ Performance Metric	Target Date (Month/ Year)	Participants/Contributors/ Partners	Key Dependencies/ Risks
caGRID and CDE Validation of caGrid and CDE architectures as a means of establishing virtual biospecimen banks.	Grid enablement of all core applications. Completion of security architecture and processes Prototypes showing access to distributed instances of the same application and between applications.	6/2007	DSIC, VCDE and DSIC workspaces	Timely release and availability of robust and fully functional enabling components
Goal 4 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Month/ Year)**	**Participants/Contributors/ Partners**	**Key Dependencies/ Risks**
Compliance In collaboration with other workspaces, ensure compliance with 21 Code of Federal Regulations (CFR) Part 11 and Health Insurance Portability and Accountability Act (HIPAA) requirements. The purpose of this goal is to help facilitate a common architecture and guideline documents for all workspaces, taking into consideration the nuances and requirements of the various domains	TBD	12/2007	All workspaces in caBIG™, the Office of Biorepositories and Biospecimen Research (OBBR)	Effective communication across workspaces Agreement of the requirements of the federal regulations and guidelines Access to appropriate resources, both personnel and financial

Program/Initiative: TBPT WS --New tool development (NTD)				
Goal 1 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Month/Year)**	**Participants/Contributors/ Partners**	**Key Dependencies/Risks**
Imaging Tools Development of image analysis and whole slide imaging tools in collaboration with the caBIG™ IMAG WS	Codify whole slide image and spectral standards Create imaging algorithms for target segmentation and quantization of a. single proteins b. multiple proteins Integrate whole slide images with clinical annotation module	TBD	TBPT, IMAG, ICR and CTMS Workspaces	Agreement on methodologies, priorities and timelines Appropriate individuals involved to be able to create spectral imaging standards and analysis algorithms
Goal 2 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Month/ Year)**	**Participants/Contributors/ Partners**	**Key Dependencies/ Risks**
TMA Development of a Tissue Microarray Suite (caTMA) for integration into the caTISSUE components already in place (caTIES, caTISSUE Annotation caTISSUE Core and paraffin archive). This module should not only include images, but image analysis, biomarker data, links to CTMS/ICR and clinical outcomes to assist in the selection of the tissue specimens for construction of TMAs and downstream analysis of TMA data.	TMA standards for slide creation, representation, and reporting Development of TMA Object Model for inclusion with Experimental Annotation Module TMA analysis algorithms	TBD	TBPT, ICR, CTMS and IMAG Workspaces	Agreement on methodologies, priorities and timelines

Goal 3 Name & Description	Completion Indicator/ Performance Metric	Target Date (Month/ Year)	Participants/Contributors/ Partners	Key Dependencies/ Risks
House keeping Development of essential house keeping components to the caTISSUE biospecimen management suite. These components help tissue bank managers provide appropriate services to their patrons and their administrators.	Shipping/Receiving Billing Batch processing/bar coding	06/07 12/07 03/08	TBD Output from NBN pilot Cooperative Groups Developers Adopters	Development of standards Agreement on a generic API

Program/Initiative: TBPT WS --Outreach (OR)				
Goal 1 Name & Description	**Completion-Indicator/ Performance Metric**	**Target Date (Month/Year)**	**Participants/Contributors/ Partners**	**Key Dependencies/Risks**
Wider Adoption Have non-funded academic, research, and industry organization use caBIG™ tissue banking tools	Five organizations using caBIG™ tissue banking tools	3/07	TBD	Lack of interest in individual tools; organizations defer use for until a cross-workspace data sharing tool is available Ineffective organizational structure that would inhibit new members from participating in workspace.
Goal 2 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Month/ Year)**	**Participants/Contributors/ Partners**	**Key Dependencies/ Risks**
Case Studies Implement cases studies in caBIG™ tissue banking tool use (i.e., pay a number of adopter to use tool; demonstrate tool use in scientific research)	TBD	TBD	TBD	TBD
Goal 3 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Month/ Year)**	**Participants/Contributors/ Partners**	**Key Dependencies/ Risks**
Harmonization Support NCI international biobank harmonization initiatives	Establishment of international standards for exchanging biobank data.	TBD	TBD	TBD

Goal 4 Name & Description	Completion Indicator/ Performance Metric	Target Date (Month/ Year)	Participants/Contributors/ Partners	Key Dependencies/ Risks
External Initiatives Reach out to existing NCI funded biospecimen management activities outside of caBIG™	Work with Cooperative groups, EDRN, SPIN and other related NCI programs to enhance and standardize biospecimen management practices	TBD	TBPT, EDRN, NBN, SPIN, and other NCI funded collaborative consortium dealing with biospecimen management.	Willingness to work together Appropriate environment and support (from institutions and NCI) to facilitate inter-group collaborations.
Goal 5 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Month/ Year)**	**Participants/Contributors/ Partners**	**Key Dependencies/ Risks**
Federation Proof of concept of federated biospecimen network	Leverage NBN activities to test out the caBIG™ applications to carry out real collaborative clinical studies	09/07	TBPT workspace members, NBN Adopters of caTISSUE applications	TBPT applications appropriate for NBN use. Established NBN workflows in mature enough state to support research

12.0 In Vivo Imaging Workspace

The primary goal of the In Vivo Imaging (IMAG) WS is to advance imaging informatics by creating, optimizing, and validating software tools and modeling methods to extract meaning from in vivo imaging data, thereby improving outcomes for patients with cancer or pre-cancer.

The IMAG WS will create a set of interoperable tools that will ultimately provide the cancer research community with more choices, and support modular and interoperable software architecture. The IMAG WS will also enable the creation of an interoperable system that allows widespread utilization of meaningful in vivo imaging data and metadata.

To support these goals, the IMAG WS will:

- Develop common models in the IMAG WS areas of interest, agree on a robust set of computable data standards, and develop and/or adopt messaging standards, interchange formats and common APIs

- Promulgate, maintain, refine, and evolve interoperable in vivo imaging informatics data standards (e.g., HL7, C-DISK) to ensure availability of imaging data to the research and clinical communities

- Create guidelines for an extensible in vivo image transmission infrastructure that will continue to be expanded and extended throughout the cancer research and clinical communities

- Create enabling imaging tools, modeling methods, and other related systems that will support multiple cancer research sites in their efforts to realize greater value in their cancer research endeavors by using the imaging network

- Assure that contracted IMAG WS participants have access to archived data as appropriate

- Encourage the academic and research communities to develop and validate tools and modeling methods using caBIG™ resources for targeted applications, and permit NCI to identify promising tools that might be incorporated into NCI funded clinical trials

In Years 1 and 2, the IMAG WS will focus on creating a Reference Research Workstation. The WS will also perform a gap analysis with the NCI Archive related to their current work with Core SDK for Imaging Integration into caBIG™, Core Middleware development, Image Acquisition and Redistribution Software, and Grid Platform for CAD Evaluation. The Workspace will work to fill the gaps within these above mention projects. The WS will seek guidance from George Komatsoulis, the NCI VCDE WS facilitator, with respect to gaps to be filled by the IMAG WS on current VCDE WS work, including adding ACRIN Data Collection Methods to the caDSR, Harmonization with EVS and RadLex, as well as adding Digital Imaging and Communications in Medicine (DICOM) Elements to caDSR and RadLex/EVS.

IMAG SIG Descriptions

SIG Name	SIG Purpose/Description
Software SIG	The goal of the Software SIG is to create and adapt open source software tools to promote and enhance the use of imaging in cancer research. The primary foci of the SIG are tools for image acquisition, management and analysis for use in clinical trials. The SIG will identify existing tools, and define requirements for new, open source tools that need to be developed. Based on the results of an initial workshop at the IMAG WS face-to-face meeting in December 2005, the Software SIG will begin work on the following items: 1. Viewing and annotation software that can make use of the caBIG™ grid infrastructure to retrieve images and information from a distributed database. 2. Image acquisition and redistribution software to acquire de-identified data from multiple sites and redistribute this data to multiple reader/analysis sites using the caBIG™ grid infrastructure 3. Database resources and software for change analysis including methodologies for software and algorithm validation.
Standards and Interoperability SIG	The mission of the Standards and Interoperability SIG is to: 1. Explore the needs of the image based clinical trials community 2. Identify gaps between identified needs and existing standards and practices 3. Foster the development of informatics tools to fill these gaps.
Testbed SIG	The mission of the Testbed SIG is to exhibit a comprehensive Testbed, Radiological Society of North America (RSNA) Grid that will demonstrate coordinated Radiological image viewing, annotation and CAD processing carried out between geographically dispersed locations. RSNA Grid will use DICOM and IHE compliant open-source caGrid middleware. caBIG™ is a voluntary community effort, sponsored by the National Cancer Institute (NCI) Center for Bioinformatics, to create an informatics infrastructure that facilitates research through sharing of data, software, and expertise.

Vocabularies and Common Data Elements SIG	The scope of the VCDE SIG is the creation, adoption, and use of terminologies, ontologies, and common data elements for medical imaging. The mission of the VCDE SIG is (1) to promote, support, develop, and evaluate standards-based vocabularies, ontologies, and CDEs for radiology and allied imaging fields, and to complement and augment the activities that are underway in other SIGs within the IMAG and VCDE WS, as well as throughout the entire caBIG™ community. This includes participation in the design of the Testbed and providing the vocabulary-related elements required by the Testbed. In particular, the VCDE SIG, in collaboration with other SIGS, will help develop the standards for creating, storing, and retrieving image metadata and image annotations; will harmonize vocabularies and common data elements developed in the VCDE SIG with those being created by the VCDE WS; and will develop VCDE-specific tools and resources that can be deployed on the grid to help realize the strategic vision of caBIG™.

IMAG WS Strategic Goals

Program/Initiative: IMAG WS --Enhance the RSNA caBIG™ GRID Testbed Exhibit RSNA 2006				
Goal 1 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Month/Year)**	**Participants/ Contributors/Partners**	**Key Dependencies/Risks**
Demonstrate the caBIG™ caGRID Testbed at the 2006 RSNA convention.	Positive reception of Testbed demo at RSNA 2006 Annual Meeting.	11/06	Ohio State University Imaging Testbed SIG ARCH WS	Must be able to identify overlaps with existing ARCH WS, risk of spending funds on work that is already being done.
Goal 2 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Month/Year)**	**Participants/ Contributors/Partners**	**Key Dependencies/Risks**
Complete gap analysis of work already being conducted in other caBIG™ Workspaces.	Creation of a document detailing work that could be funded towards the caBIG™ caGRID Testbed, which is not redundant to work that, is already being funded and conducted in caBIG™.	Annual Meeting (4/06)	Imaging Testbed SIG ARCH WS University of Maryland	Assure that current needs are clearly identified and document them, so a new project does not fund work that is already being confounded and conducted.

Program/Initiative: IMAG WS --Support the NCI Archive's Goals to Avoid Duplication of Current NCI Archive Work				
Goal 1 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Month/Year)**	**Participants/ Contributors/Partners**	**Key Dependencies/Risks**
Arrange a face to face meeting with key members of NCI Archives and interested SMEs to perform gap analysis of current NCI Archives work on these projects.	Creation of a document detailing the work that could be funded towards completion of these projects.	4/06	NCI Archive Representatives Funded SME/SW SIG participants	Assure that current needs are clearly identified and documented so a new project does not fund work that is already being confounded and conducted.

Goal 2 Name & Description	Completion Indicator/ Performance Metric	Target Date (Month/Year)	Participants/ Contributors/Partners	Key Dependencies/Risks
Fund projects that will fill the gaps in the projects mentioned above.	Issuance of sole source or competitive RFPs.	4/06	NCI BAH	SOWs must clearly define that gaps that are needed to be filled, so that fund are not expended on work that is already being conducted by the NCI Archives.

Program/Initiative: **IMAG WS --Partner with VCDE WS to Create an Ontology of Cancer Imaging**				
Goal 1 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Month/Year)**	**Participants/ Contributors/Partners**	**Key Dependencies/Risks**
Partner with VCDE SIG and VCDE NCI facilitator to identify scope, objectives, and require outputs, as well as assure there are no redundancies in funded work.	Issuance of sole source or competitive RFPs that detail work that is needed and not redundant, as well as justifiably funded (at least partially) by VCDE Workspace.	4/06	George Komatsoulis Mike Keller John Dorries Eliot Siegel David Kupferschmid Paul Mulhern Members of Imaging VCDE and SIO SIG.	Assurance that work is clearly defined as individual of existing VCDE Workspace work. Risks include funding work that overlaps with existing work, and/not clearly stating work that can be justifiably funded by George Komatsoulis.

Program/Initiative: IMAG WS --Construction of a Reference Research Workstation				
Goal 1 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Month/Year)**	**Participants/ Contributors/Partners**	**Key Dependencies/Risks**
Clearly define individual projects that would be required to successfully create the workstation.	Issuance of funded projects via sole source or RFP that will facilitate the creation of the workstation.	4/06	IMAG SW SIG IMAG VCDE SIG IMAG SMEs NCI BAH	Organized data from key participants regarding what is needed to successfully construct the workstation.

Program/Initiative: IMAG WS --Incorporation of DICOM elements into caDSR and RadLex/EVS				
Goal 1 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Month/Year)**	**Participants/ Contributors/Partners**	**Key Dependencies/Risks**
Same as previous initiative.	Same as previous initiative.	Same as previous initiative.	Same as previous initiative.	Same as previous initiative.

13.0 Vocabularies and Common Data Elements Workspace

The primary goal of the Vocabularies and Common Data Elements (VCDE) WS is to evaluate and integrate systems for vocabulary, common data elements (CDE) and ontology content development, as well as software systems for content delivery. The WS is also responsible for developing standards for the representation of ontologies and vocabularies, as well as for assessments of existing systems proposed for use within caBIG™. In addition, the WS is responsible for vocabulary, CDE and ontology content development when specific and required content does not exist in a form usable by caBIG™.

As crosscutting workspaces, the VCDE and Architecture Workspaces will collaborate to address compatibility of infrastructure and promote fundamental vocabulary and data standards.

The primary objectives of the VCDE WS are to:

Liaison with other Workspaces

- Continue developing mechanisms to engage Architecture and Domain Workspaces to coordinate the delivery of semantic content
- Share Liaison Activities with other WS members

Mentor software developers and project leads in caBIG™ funded projects

- Establish training and educational activities related to the creation and management of the Vocabularies and Common Data Elements represented in the caBIG™ databases
- Formally review specific deliverables to ensure that developer's software achieves caBIG™ compatibility
- Aid developers in assembling caBIG™ compatibility review submission packages
- Conduct compatibility reviews of caBIG™ funded developer projects

Develop Data and Vocabulary Standards

- Continue to engage caBIG™ Workspaces in data standards development and recommendations and review and accept standards
- Evaluate and integrate existing Vocabularies and Common Data Elements relevant to caBIG™
- Assess the need for, and facilitate the development of new Vocabularies and Common Data Elements content
- Conduct and facilitate the review of standards submitted to the VCDE WS for consideration as a caBIG™ standard

Convene ad hoc working groups

- These groups may be tasked with researching and developing recommendations for implementing various Vocabulary and Data Standards (e.g., Missing Value Reason, Analytical services APIs, Vocabulary services APIs, Data services APIs) with other crosscutting Workspaces

VCDE WS Goals

Program/Initiative: VCDE WS --Engage the ARCH WS				
Goal 1 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Mo/Yr)**	**Participants/ Contributors/ Partners**	**Key Dependencies/ Risks**
Interaction with Architecture Establish an ongoing interaction with the ARCH WS to ensure that both workspaces' goals are strategically aligned by holding one to two joint ARCH-VCDE WS face-to face meetings/year.	Two joint meetings held per year	6/2006 10/2006	ARCH WS VCDE WS NCICB	Target dates may have to shift, depending on the development timeline of caGrid 1.0
Goal 2 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Mo/Yr)**	**Participants/ Contributors/ Partners**	**Key Dependencies/ Risks**
Joint Mentor Teams Establish ongoing joint ARCH-VCDE WS mentor teams that are provided to all caBIG™ Development Projects. These teams support the creation of interoperable data systems by working with developers to: • Review developer deliverables (e.g., Req/Spec, Use Cases, Unified Modeling Language (UML) models • Provide advice on UML modeling, model driven architecture, and interoperability. • Participate in caBIG™ software compatibility reviews	All caBIG™ Development Projects are supported by joint ARCH/VCDE Mentor Teams.	6/2006	ARCH WS VCDE WS NCICB	Dependencies: 1. Availability of sufficient mentors in the two crosscutting workspaces Risks: 1. Developer projects ignore advice from mentor teams 2. Insufficient training of mentor teams.

Goal 3 Name & Description	Completion Indicator/ Performance Metric	Target Date (Mo/Yr)	Participants/ Contributors/ Partners	Key Dependencies/ Risks
Joint Small Working Groups Establish 6 joint ARCH-VCDE small working groups to support development of infrastructure for caGrid 1.0	Six groups established in the following areas: 1. Security 2. Workflow 3. LexGrid/Vocabularies 4. Analytical and Data Services Metadata Model 5. caBIG™ Tools Registry 6. Data Provenance Workgroups participate in definition of requirements and development of caGrid 1.0 infrastructure	10/06	ARCH WS VCDE WS NCICB	Risks: 1. Lack of joint participation could cause development of caGrid components that are not sufficiently robust for full semantic interoperability.
Goal 4 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Mo/Yr)**	**Participants/ Contributors/ Partners**	**Key Dependencies/ Risks**
Architecture Liaisons Official VCDE WS delegation liaisons identified for all ARCH WS Face-to-Face meetings and bi-weekly teleconferences	Liaisons to bi-weekly teleconferences identified Liaisons to ARCH WS meetings identified	Ongoing	VCDE liaisons to ARCH WS	None identified

Goal 5 Name & Description	Completion Indicator/ Performance Metric	Target Date (Mo/Yr)	Participants/ Contributors/ Partners	Key Dependencies/ Risks
Service Metadata Work with ARCH WS to design and implement Service Metadata for data, analytical service and vocabulary nodes.	1. Ontology of computational methods in biomedical informatics created in NCI thesaurus	3/2006	ARCH WS VCDE WS NCI Enterprise Vocabulary Services (EVS) staff caBIG™ developers	Dependencies: 1. Service metamodel implementation is dependent on creation of computational method ontology and metamodel design **2.** Vocabulary service metamodel is dependent on progress and adoption of LexGrid server in caBIG™ Risks: 3. Inadequate service metamodel will inhibit efficient discovery and advertising of services **4.** Inadequate vocabulary service metamodel will inhibit efficient discovery of vocabulary content
	2. Service metamodel design for data and analytical nodes finalized for caGrid 1.0	4/2006	ARCH WS VCDE WS caDSR team	
	3. Service metamodel components implemented in caDSR and GME	6/2006	ARCH WS VCDE WS caDSR team	
	4. Analytical service applications registered within caGrid	6/2006	ARCH WS/VCDE WS participants, NCI EVS staff, caDSR team, caGrid team	
	5. Vocabulary service applications registered within caGrid	TBD	TBD	

Goal 6 Name & Description	Completion Indicator/ Performance Metric	Target Date (Mo/Yr)	Participants/ Contributors/ Partners	Key Dependencies/ Risks
Best Practices Codify best practices for data standards, UML modeling, software design and development, semantic integration and interoperability.	8 best practices available to caBIG™ developers on the web site by 12/2006 4 from ARCH WS 4 from VCDE WS 1. UML modeling 2. Semantic Integration 3. CDE Standards Package	12/2006	VCDE WS ARCH WS Best Practices SIG TRNG WS	Dependencies: 1. Cooperation of ARCH WS essential for goal of 8 best practices by end of year Risks 1. Lack of consensus within VCDE or Architecture WS 2. Insufficient training in best practices among domain workspace participants

Program/Initiative: VCDE WS --Terminologies				
Goal 1 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Mo/Yr)**	**Participants/ Contributors/ Partners**	**Key Dependencies/ Risks**
LexGrid Terminology Deploy the open source LexGrid terminology server for the use of caBIG™ participants and the cancer research community	LexGrid terminology server deployed and running at NCI	12/2006	Mayo Clinic EVS NCICB	Dependencies: 1. LexGrid development schedule 2. EVS Deployment schedule 3. Service metamodel for vocabularies (Goal 5) Risks: 1. Identification of appropriate adopter sites for LexGrid adoption
	Grid enablement of LexGrid servers	12/2006	Mayo Clinic caGrid team EVS team LexGrid Adopters	
	Up to 2 adopters of LexGrid serving terminologies not currently provided by EVS LexGrid node	12/2006	Mayo Clinic Cancer Centers	

Goal 2 Name & Description	Completion Indicator/ Performance Metric	Target Date (Mo/Yr)	Participants/ Contributors/ Partners	Key Dependencies/ Risks
Metrics Develop and ratify metrics for the evaluation of the suitability of vocabularies and terminologies as caBIG™ standards	National Center for Biological Ontologies engaged as part of determination of metrics and governance process Conduct several formal reviews of vocabularies and terminologies (candidates are NCI Thesaurus and GO). These reference implementations will be used to suggest possible metrics Design review process based on experience of reference implementations Review Process accepted and published on Website. Review Process implemented in VCDE WS	6/2006	VCDE WS EVS staff	Dependencies 1. Availability of groups willing to develop possible metrics

Goal 3 Name & Description	Completion Indicator/ Performance Metric	Target Date (Mo/Yr)	Participants/ Contributors/ Partners	Key Dependencies/ Risks
Standards for Compatibility Vocabularies and terminologies are designated as caBIG™ standards for purposes for caBIG™ compatibility	Respond to Domain WS requests to review Vocabularies as "caBIG™ Standard Terminology" and have them as standards within three months of request	9/2006	VCDE WS EVS staff Domain Workspaces	Dependencies: 1. Dependent upon WS consensus on review process and artifacts needed for review 2. Dependent upon Domain WS in caBIG™ to nominate terminologies as standards

Program/Initiative: VCDE WS --CDE Creation and Harmonization				
Goal 1 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Mo/Yr)**	**Participants/ Contributors/ Partners**	**Key Dependencies/ Risks**
HL7 Datatypes Make HL7 complex datatypes available in the caDSR for use by domain modelers	20 complex datatypes available for use by domain workspace modelers	12/2006	VCDE WS caDSR curators software developers	Dependencies: 1. Identification of the highest impact HL7 datatypes 2. Maintenance of the mapping between HL7 datatypes and their caDSR representations
Goal 2 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Mo/Yr)**	**Participants/ Contributors/ Partners**	**Key Dependencies/ Risks**
Data Standards Ratify additional data standards nominated by the domain workspaces.	100 additional CDE standards established 1. Demographic Data a. Address b. Organization c. Marital Status d. Religion 2. ICR Projects a. bioPAX b. Gene Identifiers c. MAGE-ML d. mzXML e. Taxonomy 3. CTMS Projects a. Units of measure b. Core BRIDG Classes c. Pharmacology 4. TBPT Projects a. CAP Protocols	12/2006	Domain Workspaces VCDE WS	Dependencies: 1. A flow of proposed standards from the domain workspaces Risks: 1. Insufficient consensus within domain workspaces to nominate data standards 2. Insufficient bandwidth in the VCDE workspace to review standards promptly.

Goal 3 Name & Description	Completion Indicator/ Performance Metric	Target Date (Mo/Yr)	Participants/ Contributors/ Partners	Key Dependencies/ Risks
Metadata Curation Best Practices Complete and deploy Metadata Curation Best Practices Manual	Metadata curation manual deployed and in use within caBIG™	5/2006	NCI Context administrators VCDE WS TRNG WS	None Identified

14.0 Architecture Workspace

The primary goal of the Architecture (ARCH) WS is to ensure consistent application of caBIG™ development principles within the caBIG™ community to facilitate integration and implementation activities. The ARCH WS develops architectural standards, syntactic interoperability requirements, and compatibility review criteria; provides architectural assistance to the domain workspaces; and develops Grid Infrastructure (caGrid).

As crosscutting workspaces, the VCDE and ARCH Workspaces will consolidate their goals and collaborate to address compatibility of infrastructure and promote fundamental vocabulary and data standards.

The primary objectives of the ARCH WS are to:

- Develop the caGrid production infrastructure
- Develop specification documents for building "gold" compliant systems
- Develop tools that support the development of "gold" compliant data and analytical services
- Liaison with other Workspaces
    - Continue to develop mechanisms for engaging VCDE and Domain Workspaces to coordinate and ensure syntactic interoperability
    - Share Liaison Activities with other WS members
- Mentor software developers and project leads in caBIG funded projects
    - Establish training and educational activities related to syntactic interoperability
    - Formally review specific deliverables to ensure that developer projects achieve caBIG™ compatibility
    - Aid developers in assembling caBIG™ compatibility review submission packages
    - Conduct compatibility reviews of caBIG™ funded developer projects
- Convene ad hoc working groups (e.g., Identity Management and Federation Working Group) which may be tasked with researching and developing recommendations for implementing various architectural standards with other crosscutting Workspaces

ARCH SIG Descriptions

SIG Name	SIG Purpose/Description
Best Practice	The Best Practice SIG is a collaboration between the ARCH and VCDE workspaces. The SIG focuses on developing best practices and Standard Operating Procedures (SOPs) that will aid caBIG™ developers in reaching Silver Compatibility (e.g., core software development, grid enablement, semantic interoperability). The needs of the caBIG™ community will drive the development of these best practices and SOPs.

ARCH WS Goals

Goal 1 Name & Description	Completion Indicator/ Performance Metric	Target Date (Month/Year)	Participants/ Contributors/Partners	Key Dependencies/Risks
Develop caGrid 1.0	caGrid 1.0 Requirements Presented to the ARCH WS and released to the community	TBD	caGrid 1.0 Team/caBIG™ ARCH WS/Domain Workspace Use Case Providers	Availability of Use Cases from Domain Workspaces
Goal 2 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Month/Year)**	**Participants/ Contributors/Partners**	**Key Dependencies/Risks**
Develop caGrid 1.0 – Design Documentation	caGrid 1.0 Design Documents released	TBD	caGrid 1.0 Team/caBIG™ ARCH WS/Domain Workspace Use Case Providers	Timely completion of Use Cases / concurrent demand to develop Prototype of caGrid 1.0 for the Annual Meeting
Goal 3 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Month/Year)**	**Participants/ Contributors/Partners**	**Key Dependencies/Risks**
Develop caGrid Beta 1.0	Release of caGrid Beta 1.0 / caGrid 1.0 Beta (Browser Link) available on Public Website for caBIG™ Community to use	Jul-06	caGrid 1.0 team / caBIG™ ARCH WS	Successful approval of caGrid Design Documents, receipt of feedback on the caGrid 1.0 Prototype from the Annual Meeting/Integration of the caGrid components, timely feedback from the caBIG™ Community

Goal 4 Name & Description	Completion Indicator/ Performance Metric	Target Date (Month/Year)	Participants/ Contributors/Partners	Key Dependencies/Risks
Develop caGrid Production Release Ver 1.0 • Analytical Service Enhancements • Security Infrastructure • Metadata Management • Workflow Middleware • caGrid Workflow Language • Object Identifiers • Data Service Enhancement • caGrid 1.0 Portal • Workflow Adopter – Implementation	Release of caGrid / caGrid 1.0 Beta (Browser Link) available on Public Website for caBIG™ Community to use	Oct-06	caGrid 1.0 team / caBIG™ ARCH WS	Successful approval of caGrid Design Documents, provision of feedback on the caGrid 1.0 Prototype from the Annual Meeting/Integration of the caGrid components, timely feedback from the caBIG™ Community
Goal 5 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Month/Year)**	**Participants/ Contributors/Partners**	**Key Dependencies/Risks**
Develop caGrid 1.0 – Technical Guide	Release of caGrid / caGrid 1.0 Beta (Browser Link) available on Public Website for caBIG™ Community use	Oct-06	caGrid 1.0 team / caBIG™ ARCH WS	Successful approval of caGrid Design Documents, provision of feedback on the caGrid 1.0 Prototype from the Annual Meeting/Integration of the caGrid components, timely feedback from the caBIG™ Community
Goal 6 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Month/Year)**	**Participants/ Contributors/Partners**	**Key Dependencies/Risks**
Develop caGrid 1.0 – User Guide	Release of caGrid 1.0 – User Guide available on Public Website for caBIG™ Community use	Oct-06	caGrid 1.0 team / caBIG™ ARCH WS	Successful approval of caGrid Design Documents, provision of feedback on the caGrid 1.0 Prototype from the Annual Meeting/Integration of the caGrid components, timely feedback from the caBIG™ Community

Goal 7 Name & Description	Completion Indicator/ Performance Metric	Target Date (Month/Year)	Participants/ Contributors/Partners	Key Dependencies/Risks
Develop caGrid 0.5 to 1.0 Guide	Release of caGrid 1.0 – User Guide available on Public Website for caBIG™ Community use	Oct-06	caGrid 1.0 team / caBIG™ ARCH WS	Successful approval of caGrid Design Documents, provision of feedback on the caGrid 1.0 Prototype from the Annual Meeting/Integration of the caGrid components, timely feedback from the caBIG™ Community
Goal 8 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Month/Year)**	**Participants/ Contributors/Partners**	**Key Dependencies/Risks**
Develop caGrid 1.0 Specification	Release of the Specifications	Oct-06	caGrid 1.0 team / caBIG™ ARCH WS	Release of caGrid 1.0
Goal 9 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Month/Year)**	**Participants/ Contributors/Partners**	**Key Dependencies/Risks**
Formalize and implement caBIG™ certification program	Release of caGrid 1.0 & the Release of Gold Level Certification Program	Mar-07	NCICB	Release of caGrid 1.0
Goal 10 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Month/Year)**	**Participants/ Contributors/Partners**	**Key Dependencies/Risks**
Develop caGrid SDK Connector	Release of SDK Connector on caBIG™ Website / Available for download	Apr-07	NCICB	Enhancement of caCORE SDK
Goal 11 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Month/Year)**	**Participants/ Contributors/Partners**	**Key Dependencies/Risks**
Collect user Feedback on Grid Performance	Usage of Analytical Services – performance improvement	Apr-07	caGrid 1.x Team / ARCH WS	Computational Resources (eg. Lawrence Berkeley Lab)

Goal 12 Name & Description	Completion Indicator/ Performance Metric	Target Date (Month/Year)	Participants/ Contributors/Partners	Key Dependencies/Risks
Develop caBIG™ Compatibility Guidelines Document Version 3.0	Release of caBIG™ Compatibility Guidelines Document Version 3.0 / caBIG™ Website	Apr-07	NCICB	Release of caGrid 1.0 Specifications

15.0 Training Workspace

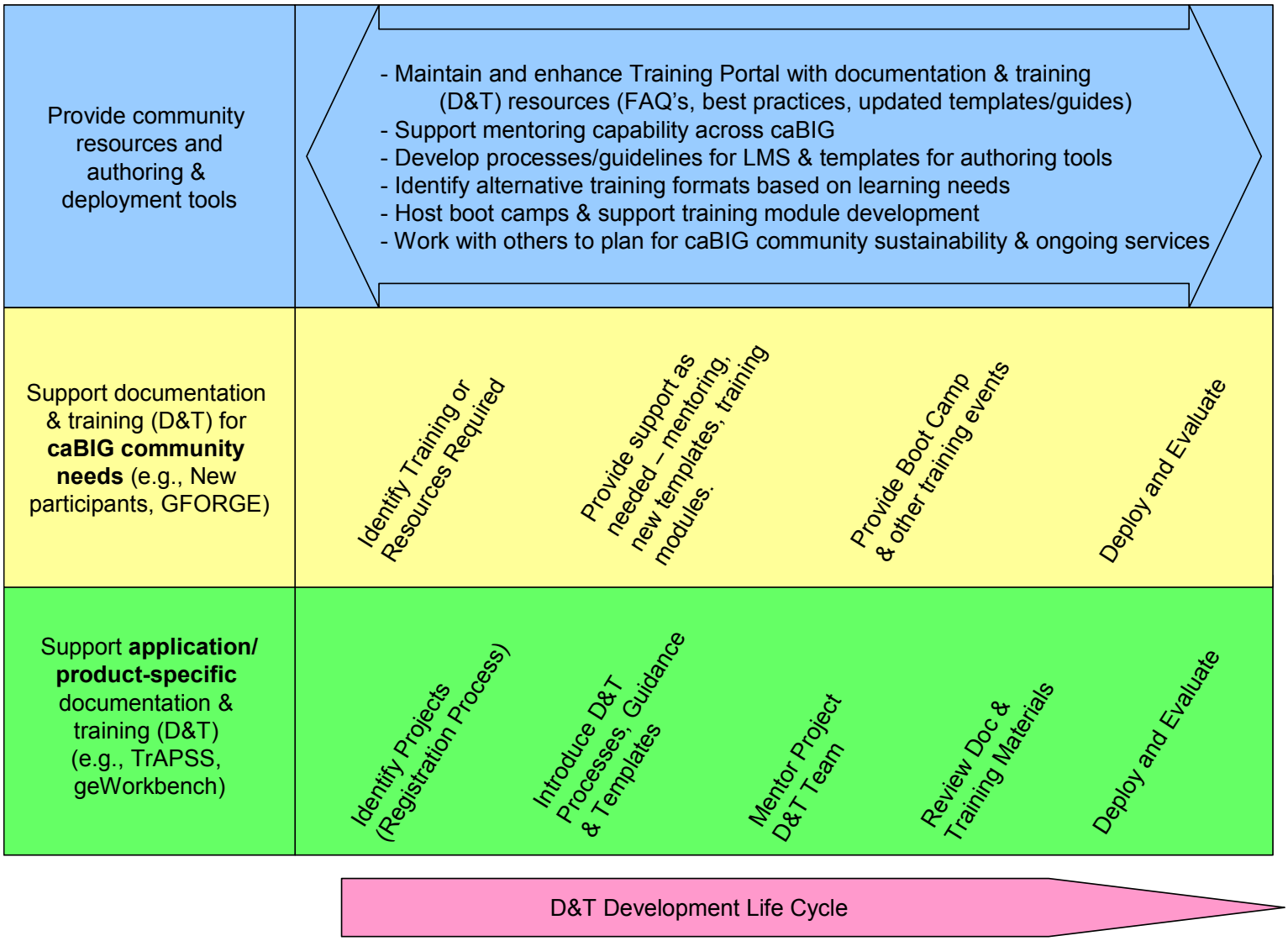
The primary goal of the Training (TRNG) WS is to support the creation and dissemination of documentation and training materials for caBIG™-related projects and community-wide resources. The TRNG WS facilitates widespread adoption, dissemination, and use of caBIG™ interoperable tools, standards, and data sets within the larger cancer and biomedical communities.

The primary objectives of the TRNG WS are:

- Developing and deploying processes, guidelines, and templates for application/product-specific documentation and training
- Providing processes, guidelines, and templates to support the creation and delivery of general training modules on caBIG™ for caBIG™ participants and community members, including information about the program, its requirements, and its business processes
- Actively engaging the caBIG™ community to ensure that documentation and training templates are used, resulting in robust documentation and training for projects and a common "look and feel" across caBIG™
- Providing a variety of training, boot camp, and mentoring services to those involved with caBIG™ documentation and training
- Reviewing documentation and training materials
- Facilitating the compilation of web-based resources such as: Best Practices, Frequently Asked Questions (FAQs), and other resources to support the caBIG™ community
- Developing resources and learning environments that support future training capabilities across the program. These activities include working with NCI to identify and/or deploy environments that support online and/or computer based training, and exploring new ways to ensure that training solutions are scaleable as the community grows.

The strategic goals, described in the following section, directly support the mission of the TRNG WS. The following schematic illustrates how TRNG WS activities and goals relate to one another.

Figure 2. Mapping TRNG WS Services and Goals



TRNG SIG Descriptions

For 2006, the TRNG WS proposes streamlining and renaming its previous SIG structure into three new groups, to build on past successes and reflect the priorities and emphasis in the months ahead. SIG's in operation over the past year will be incorporated into these groups.

SIG	SIG Description/Purpose
Mentoring SIG	To provide preparation, support, and resources for mentors operating within the caBIG™ community – both within the TRNG WS and for other workspaces. To gather best practices and lessons learned related to mentoring to provide feedback to existing mentors, and to support the development of future mentors. SIG resources and activities will facilitate the creation, implementation, and evaluation of positive mentoring relationships that advance the growth of caBIG™. TRNG WS mentors will provide feedback to the SIG on existing processes, guidelines, and templates and lessons learned through the mentoring process.
Documentation/ Training Review SIG	To coordinate the review of documentation and training materials created within caBIG™. To gather best practices and answer FAQs related to documentation preparation and training materials development, to provide feedback to those preparing these materials, and to continue enhancing the capability of documentation and training developers. To continue to refine and update guidelines and templates based on participant feedback.
Community Resources SIG	To manage and coordinate the development, deployment, and utilization of resources and processes that facilitate learning across caBIG™. Ongoing activities include: coordinating with NCICB to ensure the effective use of a Learning Management System (LMS) and courseware authoring environment to support caBIG™ needs; coordinating updates with the caBIG™ Training Portal; working with other workspaces/SIG's to coordinate and publicize best practices and FAQs; generating (or facilitating the generation of) introductory materials and/or training modules to support those new to caBIG™ (e.g., caBIG™ Primer); and developing and delivering Boot Camp events to instruct existing participants in the use of caBIG™ resources, templates, and infrastructure.

TRNG WS Goals

Program/Initiative: TRNG WS – Publicize Guidelines, Templates and Processes				
Goal 1 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Mo/Year)**	**Participants/ Contributors/Partners**	**Key Dependencies/Risks**
Evaluation of Effectiveness Evaluate the effectiveness of existing documentation and training (D&T) guidelines, templates and processes.	Conduct evaluations and interviews with developers to gauge the ease of use and time required for D&T development.	Within 1 month of project completion of D&T.	D&T Review SIG, caBIG™ Adopters and Developers	Feedback depends on the availability of caBIG™ Adopters and Developers to participate in evaluation.
Goal 2 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Mo/Year)**	**Participants/ Contributors/Partners**	**Key Dependencies/Risks**
Evolution of Guidelines, Templates, and Processes Evolve guidelines, templates and processes as needed based on feedback.	Existing guidelines, templates and processes revalidated quarterly, with updated materials posted within one quarter of the identified need.	Updates issued within 1 quarter of need identification	D&T Review SIG	TRNG WS work depends on feedback about the existing templates, so that improvements can be made as appropriate.
Goal 3 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Mo/Year)**	**Participants/ Contributors/Partners**	**Key Dependencies/Risks**
Publicity of Guidelines, Templates, and Processes Publicize D&T guidelines, templates and processes through workshops/ conferences, outreach to other workspaces, and website postings.	Number of conference/meeting presentations conducted related to D&T guidelines, templates and processes.	All workspaces/ SIG's briefed by 9/06.	D&T Review SIG, Domain Workspaces	Depends on the availability of resources to host/plan workshops/ conferences.

Goal 4 Name & Description	Completion Indicator/ Performance Metric	Target Date (Mo/Year)	Participants/ Contributors/Partners	Key Dependencies/Risks
Training Boot Camps Continue hosting Training Boot Camps to teach caBIG™ participants how to develop D&T materials according to existing guidelines, templates and processes.	Use questionnaires surveys, and interviews to assess the need and post-event success of Boot Camps. Hold Boot Camps as needed to support training and documentation capability development.	Ongoing	D&T Review SIG; Community Resources SIG, NCICB, Subject Matter Experts (SMEs)	Depends on the availability of resources to host/plan boot camp events, as well as feedback from community members.
Goal 5 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Mo/Year)**	**Participants/ Contributors/Partners**	**Key Dependencies/Risks**
Bronze, Silver, and Gold Compatibility Guidelines Finalize and release Bronze, Silver, and Gold D&T Compatibility Guidelines for both legacy and new applications.	Documentation and training Compatibility Guidelines included within program-wide Compatibility Guidelines.	Concurrent with release dates of future Compatibility Guidelines	caBIG™ leaders who must approve and issue updates to Compatibility Guidelines; ARCH and VCDE WS	Release of new Compatibility Guidelines will depend on the larger caBIG™ program's release schedule for updated Compatibility Guidelines.

Program/Initiative: TRNG WS – Develop New Resources and Tools for Community				
Goal 1 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Mo/Year)**	**Participants/ Contributors/Partners**	**Key Dependencies/Risks**
Web-Based Best Practices Lead effort to publish web-based resources such as: best practices, FAQs, etc. to support the caBIG™ community	Best practices repository and FAQs posted on the caBIG™ website.	9/06	Community Resources SIG, CTMS Best Practices SIG; ARCH/ VCDE Best Practice SIG, NCICB App Support	The TRNG WS depends on the contribution of best practices and FAQs from other workspaces to support content for these resources.

Goal 2 Name & Description	Completion Indicator/ Performance Metric	Target Date (Mo/Year)	Participants/ Contributors/Partners	Key Dependencies/Risks
Decision Matrix Publish decision matrix to identify appropriate training modalities (training formats) based on content, and instructor/learner needs. This matrix will include web-based, computer-based, face-to-face, and other alternative formats.	"Decision and alternative matrix" published to guide training modality/format selection by training developers.	8/06	Community Resources SIG, NCICB-LMS Team	The type of training required may differ along the product lifecycle: Prototypes may require instructor led training, whereas a full deployment may require self-paced training for a larger audience. TRNG WS timelines will be driven by the product timelines.
Goal 3 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Mo/Year)**	**Participants/ Contributors/Partners**	**Key Dependencies/Risks**
LMS Governance and Processes Develop the governance and processes required to field the LMS as an active tool for caBIG™.	LMS governance and process documented and posted on website.	Ongoing	Community Resources SIG, NCICB-LMS Team	Use of LMS may depend on availability of licenses for caBIG™ instructor/learner communities.
Goal 4 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Mo/Year)**	**Participants/ Contributors/Partners**	**Key Dependencies/Risks**
Authoring and Hosting Environments Work with NCICB to evaluate authoring and hosting environments to store and serve training content (both for caCORE and other training) through the LMS.	Identify and post a matrix with authoring tool options and criteria for selecting them.	7/06	Community Resources SIG, NCICB-LMS Team	Options may be enhanced by the availability of open source tools. TRNG WS will work with NCICB to coordinate dates for caCORE curriculum (and other caBIG™ training) delivery through the LMS.

Goal 5 Name & Description	Completion Indicator/ Performance Metric	Target Date (Mo/Year)	Participants/ Contributors/Partners	Key Dependencies/Risks
Alternative Training Templates Develop and publish alternative training template(s) to support self-paced learning module development.	Publish template and a self-paced format module by end of 06 (e.g., web-based training) – Example: translating a caCORE module into a self-paced format	Self-paced module templates delivered by end of 2006.	Community Resources SIG, D&T Review SIG, NCICB-LMS Team	Understanding needs will be driven by availability of feedback from the community.
Goal 6 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Mo/Year)**	**Participants/ Contributors/Partners**	**Key Dependencies/Risks**
Test and Exercise Construction Build caBIG™ capability related to test and exercise construction.	Provide mini-workshops and/or tools specifically oriented towards teaching test and exercise construction.	Post materials by 10/06	Community Resources SIG	Depends on the experience of participants in the TRNG WS to build.

Program/Initiative: TRNG WS – Implement and Sustain Mentoring and Review Programs				
Goal 1 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Mo/Year)**	**Participants/ Contributors/Partners**	**Key Dependencies/Risks**
Formal Mentoring Program Establish and document a formal mentoring program that facilitates the completion of documentation and training in accordance with caBIG™ guidelines, processes and templates.	Mentoring program formally established and documented online	9/06	Mentoring SIG	TRNG WS will need to build its base of qualified mentors to ensure that demand can be met.

Goal 2 Name & Description	Completion Indicator/ Performance Metric	Target Date (Mo/Year)	Participants/ Contributors/Partners	Key Dependencies/Risks
Mentoring Requests Respond to community/project D&T mentoring requests.	Respond within two weeks to all mentoring engagements requested by the community.	Ongoing	Mentoring SIG	TRNG WS will need to continue to monitor its base of qualified mentors to ensure that demand can be met.
Goal 3 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Mo/Year)**	**Participants/ Contributors/Partners**	**Key Dependencies/Risks**
Mentoring Best Practices Establish mechanism for sharing best practices related to the mentoring process across workspaces. Post "best practices" related to mentoring.	Mentoring best practices developed and posted on website.	12/06	Mentoring SIG, VCDE, ARCH Mentoring Programs	Activities will depend on input from the community related to mentoring
Goal 4 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Mo/Year)**	**Participants/ Contributors/Partners**	**Key Dependencies/Risks**
D&T Review Requests Respond to D&T review requests as received by developers/adopters, and conduct reviews within a timeframe that supports product deployment.	Respond within two weeks to all review engagements requested by the community.	Ongoing	D&T Review SIG	TRNG WS will need to continue to monitor its base of qualified reviewers to ensure that demand can be met.

Program/Initiative: TRNG WS– Support Documentation & Training for caBIG™ Community Needs				
Goal 1 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Mo/Year)**	**Participants/ Contributors/Partners**	**Key Dependencies/Risks**
caCORE Training Support NCICB in reaching the caBIG™ community with their training in caCORE, including publicizing LMS options, evaluating the needs for boot camps, and initiating training efforts in conjunction with NCICB.	Continue to work with NCICB to schedule boot camps as needed based on demand. Administer surveys to establish need for boot camps, and administer post-boot camp surveys to identify future needs	Ongoing	All Training SIGS, ScenPro, VCDE, NCICB	The TRNG WS efforts depend on feedback from the community as to modules required, and feedback about the existing training resources. The work of TRNG WS also will be driven by the stability of caCORE as it continues to evolve.
Goal 2 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Mo/Year)**	**Participants/ Contributors/Partners**	**Key Dependencies/Risks**
Additional Training Modules Identify additional training modules required to support the caBIG™ community, and identify resources to develop that training.	Publish list of needed training modules, and match to SME's/resources that can support training development.	Quarterly Reviews	Community Resources SIG, NCICB staff, BAH staff	The labor/resources required to develop and deploy training modules may limit the number that can be produced.

Program/Initiative: TRNG WS – Plan for Future Sustainability				
Goal 1 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Mo/Year)**	**Participants/ Contributors/Partners**	**Key Dependencies/Risks**
Help Desk Support Coordinate a cross-workspace and NCICB effort to develop an approach for managing ongoing "help desk" support for applications once fielded, as well as the need for upgrades to materials as new releases and upgrades are scheduled.	Convene planning meeting to discuss, and then develop a Plan of Action.	3/07	SP WS, NCICB Applications Support, Domain Workspaces.	Depends on clear roles/ responsibilities with respect to ongoing support, and ongoing funding to provide support resources.

Goal 2 Name & Description	Completion Indicator/ Performance Metric	Target Date (Mo/Year)	Participants/ Contributors/Partners	Key Dependencies/Risks
Planning Initiate planning to support the future sustainability of the TRNG WS.	Conducting planning meeting to discuss, and then develop a plan of action.	3/07	caBIG™ leadership team.	Depends on programmatic decisions related to caBIG™ for post Year 3.

16.0 Data Sharing and Intellectual Capital Workspace

The primary goal of the Data Sharing and Intellectual Capital (DSIC) WS is to identify and then propose solutions to potential barriers resulting from law, regulation, and intellectual property interests to data and resource sharing and other collaborative work across the caBIG™ community.

Challenges include:

- Proprietary concerns. caBIG™ participants have prior existing collections of resources such as data and materials, and stand to benefit from the analyses thereof. Some participants may be reluctant to disseminate these resources broadly in a timely manner for reasons related to the potential profitability of such resources. DSIC WS addresses these barriers by identifying best practices in data sharing and other relevant agreements, and providing suggested strategies to the community. It is anticipated that the use of such practices will lower the transaction costs of sharing arrangements and promote collaborative scientific research.

- Licensing. Consistent with caBIG™'s fundamental principle of open source and open development, DSIC WS is providing the community with Open Source Software Guidelines and a Model Agreement. caBIG™ participants and their institutions may use the model agreement (or a document with identical effect) as part of their licensing arrangement for software developed with NCI funding for caBIG™. DSIC WS also receives comments about operating in an open source environment from caBIG™ participants and addresses their concerns through FAQs or white papers.

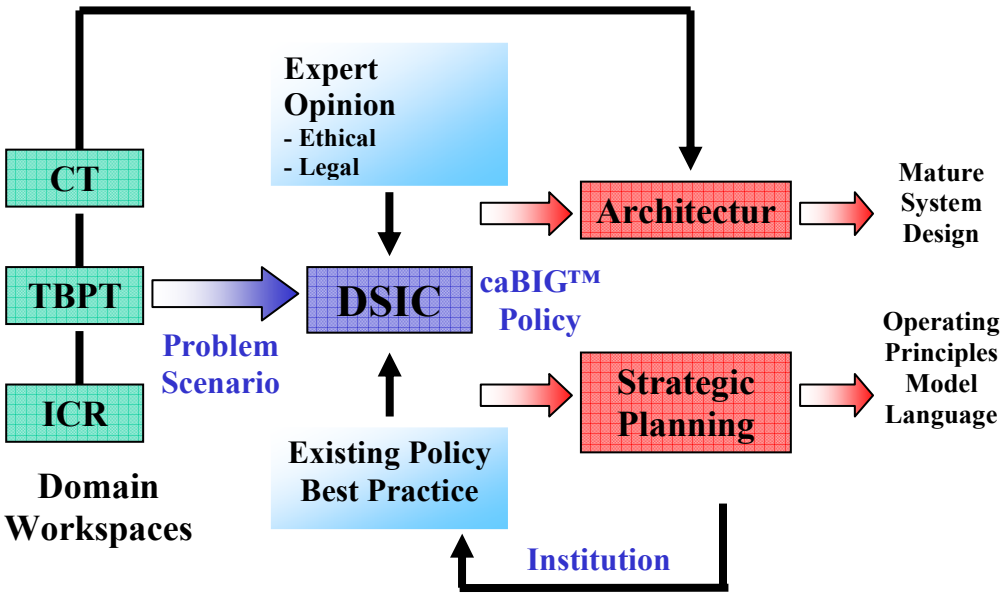
- Publications. The DSIC WS establishes policies and recommendations related to the development of documents concerning caBIG™ processes and resources. DSIC WS addresses concerns related to two types of publications. The first category is "caBIG™ Publications," defined as those documents that describe or discuss the creation, coordination, setting of policy and procedures for, and/or the maintenance of the caBIG™ initiative and its components. The second category are external publications, such as academic publications intended for publication in peer-reviewed journals that describe scientific research conducted using or leveraging caBIG™.

- Regulatory concerns. The DSIC WS seeks to provide guidance about regulatory issues to caBIG™ participants who will contribute to or obtain data from the grid. It does so by researching issues related to statutes and regulations affecting research on human subjects, such as the Common Rule for Human Subjects Research, the FDA Regulations on Human Subjects, HIPAA Privacy and Security Rules, and state, local, and institutional requirements.

- Governance issues. In response to the growing number and types of participants in caBIG™, DSIC WS has produced a document requiring disclosure of potential financial or commercial conflicts of interest by caBIG™ participants and a document that delineates expectations for participation in caBIG™ by all participants including those involved in academia, research, industry and nonprofit organizations.

Figure 3 depicts DSIC WS's relationship with other caBIG™ activities. The WS consists of representatives from over twenty institutions, and seeks input from those organizations' lawyers, researchers, software developers, patient advocates, and representatives from technology transfer and Institutional Review Board (IRB) offices.

Figure 3. DSIC WS Relationship with other caBIG™ Activities



DSIC WS will gather sample problem scenarios involving data sharing from each domain workspace. DSIC WS will then examine these scenarios in the context of existing best practices related to patient consent, confidentiality, data sharing, and intellectual property licensing. The Workspace will formulate recommendations for new guidance only when reasonable practices do not already exist. The proposed guidance will be submitted to the SP WS for review and approval. caBIG™ recommendations will be articulated in the form of guidelines, best practices, model language, and/or document templates for patient consent, software licensing, data sharing, and biospecimen exchange. These documents will be offered to caBIG™ institutions to facilitate standardized practices across institutions. Feedback from adopter institutions will aid in shaping future guidance. caBIG™ guidance will also be conveyed to the Architecture Workspace so that they may work with individual domain developers to assess technical implications for system design.

In order to most effectively provide the caBIG™ community with guidance, the WS has proposed a number of goals, and continues to assess the need for these objectives as driven by changes in the needs of particular developers and Workspaces, the legal and regulatory environment, and the human resources and intellectual capital.

DSIC SIG Descriptions

SIG Name	SIG Purpose/Description
Proprietary SIG	Identify and propose solutions for potential barriers to sharing data and materials among caBIG™ participants presented by contractual, property, and attribution-related issues of concern to investigators and institutions. These issues generally fall into three categories: (1) data sharing, (2) transfer of biospecimens and other materials, and (3) software developments issues.
Regulatory SIG	Identify and propose solutions to potential barriers to sharing data and materials among caBIG™ participants presented by federal and other laws and regulations, such as the Common Rule on Human Subjects Research, and HIPAA Privacy and Security Rules.

DSIC WS Goals

Program/Initiative: DSIC WS --caBIG™-Governance Policy Formulation				
Goal 1 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Month/ Year)**	**Participants/Contributors/ Partners**	**Key Dependencies/Risks**
caBIG™ Publications Develop a nonbinding policy on non-caBIG™ publications advising participants of the availability of the caBIG™ Publications review process at the author's request. Document will be created in response to community requests not previously addressed by the caBIG™ Publications Policy	Final release of document to the caBIG™ Web site	4/06	Dan Steinberg, Pat Weeks, Elaine Brock	Availability of contributors; conflicting expectations/requirements within the community
Goal 2 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Month/ Year)**	**Participants/Contributors/ Partners**	**Key Dependencies/Risks**
FAQ for Publication Process Develop FAQs on Publication Policies. Responses to any and all questions to the caBIG™ Publications Policy or Statement on non-caBIG™ Publications made available to the community for reference.	Final release of document to the caBIG™ Web site	4/06	Dan Steinberg, Pat Weeks	Availability of contributors; concerns from the community concerning content of the FAQs
Goal 3 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Month/ Year)**	**Participants/Contributors /Partners**	**Key Dependencies/Risks**
Security Policy and Procedures Develop security policy and procedures. Development of policies and procedures, their implementation, and the collection of program improvements/lessons learned for caGRID 0.5.1. Developed in response to strongly expressed community needs and will be used by all those who access caGRID.	Circulation of polices and procedures to users of caGRID 0.5.1; collection of process improvements	TBD	Frank Manion; Bob Robbins; Rebecca Crowley; Sharon Winters; John Houston (all tentative)	Varying views among participants and caBIG™ administrators as to the scope of the project; alignment with caGRID 1.0

Goal 4 Name & Description	Completion Indicator/ Performance Metric	Target Date (Month/ Year)	Participants/Contributors/ Partners	Key Dependencies/Risks
Open Source Software Guidelines Develop Open Source Software (OSS) Guidelines and Model Agreement. Resource for caBIG™ developers to use embodying the requirement that NCI-funded caBIG™ tools be open source. Will have usefulness to all caBIG™ product developers.	Final release of document to the caBIG™ Web site	3/06	Wendy Patterson, Elaine Brock, Pat Weeks, Cathy Innes, Patrick Jones, Eve Waterfall, Denise Lagasse	Conflicting comments received; need for technical expertise; timeliness of document given the need to address outstanding comments
Goal 5 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Month/ Year)**	**Participants/Contributors/ Partners**	**Key Dependencies/Risks**
Open Source Software Guidelines FAQs Develop FAQs on OSS Guidelines and Model Agreement. Responses to any and all questions on the OSS documents and made available to the community for reference.	Release of first round of FAQs to the caBIG™ Web site	3/06	Pat Weeks, Wendy Patterson	Availability of contributors; objections from the community to findings of the FAQs

Program/Initiative: DSIC WS --Increase Awareness and Cooperation Among caBIG™ Participants and Institutional Review Boards				
Goal 1 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Month/ Year)**	**Participants/Contributors/ Partners**	**Key Dependencies/Risks**
IRB Informational Teleconference Conduct IRB Informational Teleconference. Conduct teleconference for IRB participants at institutions affiliated with caBIG™ participants to inform them of the existence of caBIG™ and to recruit input and participation. A goal is to continue to recruit IRB and regulatory compliance experts and to solicit participation in Regulatory SIG.	Conference completed	Conference 1: 1/06 Conference 2: 2/06	Wendy Patterson, Dan Steinberg, Mark Adams, Joyce Niland	Scheduling; Adequate RSVPs from attendees

Program/Initiative: DSIC WS --Responses to Specific caBIG™ Community Questions and Concerns				
Goal 1 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Month/ Year)**	**Participants/Contributors/ Partners**	**Key Dependencies/Risks**
White Paper on Withdrawal of Consent Develop white paper on issues related to withdrawal of consent by human subjects. Audience would be caBIG™ tool developers and researchers who may come across this issue during caBIG™'s life cycle.	Final release of document to the caBIG™ Web site	TBD	TBD	Identification of participants and mode of funding
Goal 2 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Month/ Year)**	**Participants/Contributors/ Partners**	**Key Dependencies/Risks**
HPIAA Data Shielding Mechanisms FAQs Develop FAQ on use of proxy dates and related data shielding mechanisms under HIPAA. These answer would be available to all researchers in caBIG™, some of whom may face similar questions in the course of their research	Final release of document to the caBIG™ Web site	TBD	TBD	Identification of participants
Goal 3 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Month/ Year)**	**Participants/Contributors/ Partners**	**Key Dependencies/Risks**
De-identifying Protected Health Information FAQs Develop FAQs on methods of de-identifying protected health information. These answers will be available to all researchers in caBIG™, some of whom may have come across similar questions during their work.	Final release of document to the caBIG™ Web site	TBD	TBD	Identification of participants

Goal 4 Name & Description	Completion Indicator/ Performance Metric	Target Date (Month/ Year)	Participants/Contributors/ Partners	Key Dependencies/Risks
Patients' Rights FAQs Develop FAQs on patients' rights re: compelling data sharing. These answers would be available to all researchers in caBIG™, some of whom may have come across a similar question in the scope of their work.	Final release of document to the caBIG™ Web site	TBD	TBD	Identification of participants
Goal 5 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Month/ Year)**	**Participants/Contributors/ Partners**	**Key Dependencies/Risks**
Research/Treatment Consent FAQs Develop FAQ: The difference between research and treatment and implications for consent. These answers would be available to all researchers in caBIG™, some of whom may have come across a similar question in the scope of their work.	Final release of document to the caBIG™ Web site	TBD	TBD	Identification of participants
Goal 6 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Month/ Year)**	**Participants/Contributors/ Partners**	**Key Dependencies/Risks**
Permissible Uses of Data FAQs Develop FAQ: What are permissible uses of data preparatory to research? These answers would be available to all researchers in caBIG™, some of whom may have come across a similar question in the scope of their work.	Final release of document to the caBIG™ Web site	TBD	TBD	Identification of participants

Goal 7 Name & Description	Completion Indicator/ Performance Metric	Target Date (Month/ Year)	Participants/Contributors/ Partners	Key Dependencies/Risks
Data Sharing Incentives FAQs Develop FAQ on data sharing incentives. Excerpt from the white paper on data sharing practices, this FAQ will explain the potential benefits of data sharing, including increased resources, increased funding opportunities, shorter times to publication. FAQ will be help promote the use of caBIG™ resources to conduct large, multi-site trials.	Final release of document to the caBIG™ Web site	TBD	TBD	Identification of participants
Goal 8 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Month/ Year)**	**Participants/Contributors/ Partners**	**Key Dependencies/Risks**
Regulatory Issues/Problem Scenarios Predict and advise on potential regulatory issues posed by problem scenarios (describing research proposals) using caTIES previously forwarded to DSIC WS. Responses would be provided directly to the individual researcher who raised the issues in the course of our research.	Final release of document to the caBIG™ Web site	TBD	TBD	Identification of participants and mode of funding

Program/Initiative: DSIC WS --Develop White Papers on Regulated Information Exchange (RIE)				
Goal 1 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Month/Year)**	**Participants/Contributors/ Partners**	**Key Dependencies/Risks**
De-identification White Paper Develop de-identification White Paper. White Paper on best practices related to de-identification of human subjects records in order to conduct further research. The audience for this white paper is all researchers seeking to operate in a de-identified environment to ensure compliance with HIPAA, the Common Rule, and other requirements for conducting research on human subjects.	Final release of document to the caBIG™ Web site	Draft 1/06; Poster Presentation to be proposed for Annual Meeting 4/06Final 6/06	Rachel Nosowsky; Warren Kibbe; Elaine Brock; Deb Collyar; Mary Lou Smith; Dan Steinberg	Scope insufficient for community needs; complexity of integration because components are different in scope/approach
Goal 2 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Month/Year)**	**Participants/Contributors/ Partners**	**Key Dependencies/Risks**
Data Sharing White Paper Develop white paper on data sharing. Guidance to all caBIG™ participants who use caBIG™ to exchange data. Reviews sections of a model agreement and discusses incentives for sharing of data.	Final release of the document on the caBIG™ Web site	11/06	Pat Weeks and reviewers TBD	Availability of contributors and conflicting philosophies that are beyond the scope of caBIG™ to resolve.

17.0 Strategic Planning Workspace

The Strategic Planning (SP) WS assists caBIG™ with strategic planning and vision development activities. SP WS members collectively represent all of the other caBIG™ Workspaces; this structure facilitates information sharing throughout the program. WS participants help identify strategic challenges, formulate solutions, and make recommendations. Participants also provide strategic insights regarding caBIG's™ relationship and interface with other initiatives. The products of the SP WS include white papers and planning documents that help identify and prioritize caBIG™ activities. The SP WS does not utilize Special Interest Groups (SIGs); rather the workspace forms task-oriented, time-limited committees and working groups to identify and resolve strategic issues. In Year 3, the SP WS will be addressing many issues including crosscutting model harmonization, workflows, caBIG™ portal, embedding caBIG™ in the larger community, mentoring, ongoing operational support, cross-workspace communication, and 21 CFR Part 11. The SP WS will address additional topics as they are identified.

SP WS Strategic Goals

Program/Initiative: SP WS --caBIG™ Strategic Planning				
Goal 1 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Month/Year)**	**Participants/ Contributors/Partners**	**Key Dependencies/Risks**
Strategic Plan Development Develop and update the caBIG™ Strategic Plan. The Strategic Plan sets the strategic direction for caBIG™, highlights key programmatic goals, and defines performance metrics.	Strategic Plan published and available to the Community.	Ongoing	All caBIG™ Workspaces, NCICB	Completion of WS Strategic plans Cross-workspace coordination and communication

Program/Initiative: SP WS --Strategic Issue Resolution				
Goal 1 Name & Description	**Completion Indicator/ Performance Metric**	**Target Date (Month/Year)**	**Participants/ Contributors/Partners**	**Key Dependencies/Risks**
Strategic Issue Resolution Identify and resolve issues of strategic importance that arise across the program.	Issues actively tracked, identified, and resolved.	Ongoing	SP WS Members	Issues presented effectively to the SP WS Cross-workspace coordination and communication.

18.0 Appendix of Acronyms

API	Application Programming Interface
ARCH	Architecture Workspace
BAH	Booz Allen Hamilton
BRIDG	Biomedical Research Integrated Domain Group Model
caBIG™	cancer Biomedical Informatics Grid
CTMS	Clinical Trials Management Systems Workspace
CFR	Code of Federal Regulations
DSIC	Data Sharing and Intellectual Capital Workspace
EVS	Enterprise Vocabulary Services
FAQ	Frequently Asked Question
HHS	US Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act
HL7	Health Level Seven
ICR	Integrative Cancer Research Workspace
IRB	Institutional Review Board
NCI	National Cancer Institute
NCICB	National Cancer Institute Center for Bioinformatics
NIH	National Institutes of Health
RFP	Request for Proposal
RSNA	Radiological Society of North America

SIG	Special Interest Group
SME	Subject Matter Expert
SPORES	Specialized Programs of Research Excellence
SP	Strategic Planning Workspace
SOP	Standard Operating Procedure
SOW	Statement of Work
TBPT	Tissue Banks and Pathology Tools Workspace
VCDE	Vocabularies and Common Data Elements Workspace